

CABINET FOR HEALTH SERVICES RADIOACTIVE MATERIALS SECTION RADIATION HEALTH AND TOXIC AGENTS BRANCH

ATTN: VICKI D. JEFFS

THE ATTACHED RLL-1 & RLL-2 DEVICE REVIEWS INCORPORATE THE ADDITIONAL INFORMATION YOU REQUESTED IN LETTERS DATED 12/22/98 AND 12/29/98.

JAN. 12, 1999

ITEMS NOT ADDRESSED IN THE DEVICE REVIEWS

ITEM 10 - DOSE RATE ON ACCESSIBLE SURFACES INCREASED FROM 2mR/h TO 5mR/h.

WE CHANGED THE SURFACE LEVEL AFTER REVIEWING THE APPLICATION CRITERIA AND DETERMINING THAT PERSONNEL WOULD NOT TYPICALLY WORK NEAR THE DEVICE AFTER INSTALLATION, SIZE AND WEIGHT OF THE DEVICE COULD AFFECT OUR ABILITY TO MEET CUSTOMER REOUIREMENTS AND COST CONSIDERATIONS OF SHIELDING MATERIALS.

ITEM 11 - TRANSMISSION FACTOR FOR CS-137 & CO-60 FOR CALCULATIONS

CALCULATIONS HAVE BEEN REVISED TO SHOW DISTANCE FROM CENTER LINE OF THE DEVICE TO OUTER WALL (0.375 INCHES) WITHOUT CONSIDERATION OF REDUCTIONS FOR SELF-ABSORPTION AND WALL THICKNESSES.

ITEM 15 - CLARIFICATION OF EXPOSURE RATE AT ONE FOOT FOR THE RLL-1 DEVICE

THE 0.25mR/h WAS AN ERROR WHEN TYPING THE MANUAL IT HAS BEEN CORRECTED TO LESS THAN 0.5mR/h. THE 0.3mR/h WAS THE ACTUAL AS MEASURED AND CALCULATED FOR NOMINAL SOURCE ACTIVITY. THESE DEVICES UTILIZE MULTIPLE SOURCES AND OUR SOURCE SUPPLIERS GUARANTEE THE ACTIVITY OF EACH SOURCE TO +/- 10 PERCENT, SO IT IS POSSIBLE THAT WITH RANDOM SELECTION OF SOURCE CAPSULES A COMBINATION IS POSSIBLE THAT WILL EXCEED 0.3mR/h BUT WILL NOT EXCEED 0.5mR/h.

SINCERELY;

CRAIG A. CARIS QUALITY MANAGER

> MEASUREMENTS DIVISION 8050 Production Drive • Florence, Kentucky 41042 • (606) 342-8500 • FAX (606) 342-6426

. . .

DATE: 1/7/99

RONAN ENGINEERING COMPANY MEASUREMENTS DIVISION 8050 PRODUCTION DRIVE FLORENCE, KY. 41042-3028

MANUFACTURER / DISTRIBUTOR

PHONE (606) 342-8500

CONTACTS: BONAVENTURE CAHILL - V.P./GENERAL MANAGER THOMAS NIINEMETS - ASSISTANT MANAGER CRAIG CARIS - QUALITY MANAGER

DEVICE TYPE: SOURCE HOLDER

MODEL: RLL-1 SERIES

OTHER COMPANIES INVOLVED: NOT APPLICABLE

RADIOACTIVE SOURCE MODEL DESIGNATION:

ISOTOPE PRODUCTS LABORATORIES; MODEL PHI SERIES SOURCES CAPSULE A3224 - CS-137 & CO-60

AEA TECHNOLOGIES (AMERSHAM); MODEL CDC.700 CAPSULE X7 CS-137 ONLY

RADIONUCLIDES: CESIUM-137, COBALT-60

MAXIMUM ACTIVITY: 900 MICROCURIES OF CS-137 OR 200 MICROCURIES OF CO-60 NO SINGLE SOURCE TO EXCEED 90 MICROCURIES

LEAK TEST FREQUENCY: NOT REQUIRED SEE: PAGE 6

PRINCIPAL USE CODE: (D) GAMMA GAUGES

CUSTOM DEVICE: NO

CUSTOM USER: NOT APPLICABLE

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SUMMARY DESCRIPTION:

THE RONAN MODEL RLL-1 IS A LOW LEVEL SOURCE HOLDER FOR NON-CUSTOM DISTRIBUTION AS A COMPONENT OF RONAN: DENSITY, LEVEL AND WEIGH GAGES.

THE MODEL RLL-1 SERIES SOURCE HOLDERS ARE INSTALLED INTO SHIELD ASSEMBLIES APPROPRIATE TO THE SPECIFIC APPLICATION. EACH SOURCE HOLDER CONTAINS MULTIPLE SOURCES, EACH SOURCE CONTAINS NO MORE THAN 90 MICROCURIES OF CESIUM-137 OR COBALT-60. THE INDIVIDUAL SOURCES ARE ENCLOSED IN A 1/4 INCH DIAMETER STAINLESS STEEL SOURCE TUBE. THE SOURCE TUBE IS INSIDE A 3/4 INCH DIAMETER STAINLESS STEEL TUBE. STAINLESS STEEL PLUGS ARE WELDED TO THE ENDS OF THE TUBE TO PREVENT SOURCE REMOVAL.

DISTRIBUTION WILL BE TO SPECIFIC AND GENERAL LICENSEES.

WRITTEN DESCRIPTION:

THE RLL-1 SOURCE HOLDER IS CONSTRUCTED FROM A 300 SERIES STAINLESS STEEL, 1/4 INCH (6.35mm) DIAMETER SOURCE TUBE CENTERED INSIDE A 300 SERIES STAINLESS STEEL, 3/4 INCH (19mm) DIAMETER MOUNTING TUBE. BOTH TUBES HAVE A WALL THICKNESS OF 0.035 INCHES (0.89mm). ONE END OF EACH TUBE IS TIG WELDED TO A 300 SERIES STAINLESS STEEL END CAP 3/4 INCH (19mm) IN DIAMETER. THE SOURCES AND SPACERS, 0.156 INCH (3.9mm) DIAMETER CHROMIUM STEEL BALLS, ARE INSERTED INTO THE OPEN END OF THE 1/4 INCH TUBE. A SECOND 300 SERIES STAINLESS STEEL END CAP IS INSTALLED AND TIG WELDED TO THE OUTER TUBE. THE RLL-1 SOURCE HOLDER IS THEN INSERTED INTO ITS SHIELD AND THE RADIATION FIELD IS CHECKED WITH A CALIBRATED SURVEY METER TO ENSURE A FIELD LESS THAN OR EQUAL TO 5 mR/h AT 2 INCHES AND 0.50 mR/h AT ONE FOOT FROM ALL SURFACES EXCEPT THE BEAM PORT THE RADIATION FIELD AT THE SURFACE OF THE BEAM IN THE SHIELD. PORT IS CHECKED TO VERIFY THAT IT DOES NOT EXCEED 100 mR/h. UPON VERIFICATION OF THE FIELD, THE END OF THE RLL-1 SOURCE HOLDER IS TIG WELDED INTO ITS SHIELD ASSEMBLY TO MAKE AN INSEPARABLE SHIELDED ASSEMBLY; SEE ATTACHMENT 1 FIGURES A, B AND C FOR ASSEMBLY DRAWINGS. THE CAUTION/GENERAL LICENSE LABEL IS STAMPED WITH THE REQUIRED INFORMATION AND ATTACHED TO THE OUTSIDE OF THE SHIELD WITH HARDENED STAINLESS STEEL DRIVE SCREWS OR TIG WELDED TO THE SHIELD.

THE SHIELD MAY BE CONSTRUCTED FROM CARBON STEEL OR STAINLESS STEEL WITH ENCAPSULATED LEAD OR TUNGSTEN, AS REQUIRED, TO ACHIEVE A 5 mR FIELD AT 2 INCHES. THE TOP AND BOTTOM OF THE SHIELD IS STAMPED WITH DIRECTIONAL ARROWS INDICATING THE BEAM PORT. THE SHIELDS VARY IN SIZE AND CONFIGURATION BY APPLICATION. SEE ATTACHMENT 1, FIGURE A FOR SIZES AND CONFIGURATIONS.

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PRIOR TO SHIPMENT, AN AUXILIARY SHIPPING SHIELD WILL BE INSTALLED OVER THE BEAM PORT, AS REQUIRED, TO LIMIT THE FIELD ON THE FRONT FACE TO 5 mR/h AT 2 INCHES UNTIL INSTALLATION. THE SOURCE HOLDER INSTALLATION AND INSTRUCTION MANUAL DESCRIBES REMOVAL AND STORAGE OF THE AUXILIARY SHIELD AND SAFETY PRECAUTIONS TO BE OBSERVED DURING THE INSTALLATION PROCESS.

TYPICAL APPLICATION USES FOR THE RLL-1 SOURCE HOLDER ARE SHOWN IN ATTACHMENT 1 FIGURES F, G AND H.

RONAN REVIEWS EACH APPLICATION TO DETERMINE THE QUANTITY AND ACTIVITY OF SOURCES AND TO VERIFY THAT DOSE RATES AT ALL ACCESSIBLE SURFACES OF THE APPLICATION DO NOT EXCEED 5 mR/h UNDER ALL PROCESS CONDITIONS.

THE ANSI CLASSIFICATION FOR THE SOURCES IN ACCORDANCE WITH ANSI N542 IS: 77C66444 (CAPSULE A3224); 77C66445 (CAPSULE X7) ISOTOPE PRODUCTS LAB REGISTRY NO. CA406S118S. THE DIMENSIONS FOR THE A3224 CAPSULES ARE 0.12 INCHES (3 mm) IN DIAMETER AND 0.20 INCHES (5 mm) LONG. THE DIMENSIONS FOR THE X7 CAPSULES ARE 0.17 INCHES (4.5mm) IN DIAMETER AND 0.24 INCHES (6mm) LONG. THE ANSI CLASSIFICATION OF THE RLL-1 DEVICE IS 64-675-675-R2 PER ANSI N538.

DRAWINGS: SEE ATTACHMENT 1 FIGURES A, B AND C.

CONDITIONS OF USE:

THE RONAN RLL-1 SOURCE HOLDER IS USED AS A COMPONENT OF RONAN ENGINEERING INDUSTRIAL PROCESS CONTROL INSTRUMENTS FOR LEVEL, DENSITY AND WEIGH MEASUREMENTS.

TYPICAL ENVIRONMENTAL CONDITIONS ARE:

TEMPERATURE :	-40 C TO +235 C (-40 F TO +455 F)
PRESSURE:	ATMOSPHERIC
HUMIDITY:	RANGING FROM 0 TO 100%
IMPACT:	ACCIDENTAL CONDITIONS ONLY
VIBRATION:	ZERO TO 50 CPS AT 1/16" DISPLACEMENT
CORROSION:	CAN BE MODERATELY CORROSIVE, BUT NOT USED IN
	AREAS UNSUITABLE FOR STAINLESS STEEL PROTECTION
FIRE:	UNLIKELY
EXPLOSION:	UNLIKELY
VIBRATION: CORROSION: FIRE: EXPLOSION:	ZERO TO 50 CPS AT 1/16" DISPLACEMENT CAN BE MODERATELY CORROSIVE, BUT NOT USED IN AREAS UNSUITABLE FOR STAINLESS STEEL PROTECTION UNLIKELY UNLIKELY

THE SOURCE HOLDER IS CONSTRUCTED OF STAINLESS STEEL AND WILL WITHSTAND CONTINUOUS MAXIMUM OPERATING TEMPERATURES OF 235 C BEFORE STAINLESS STEEL CHANGES CHARACTERISTICS.

SINCE RADIATION LEVELS ARE ONLY 5 mR/h ON THE SURFACE AND LESS THAN 0.5 mR/h AT 12 INCHES, EXCEPT THE UNSHIELDED BEAM PORT PG. 3 OF 10 WHERE SURFACE LEVELS ARE LESS THAN 100 mR/h, NO ON-OFF MECHANISM IS REQUIRED FOR THE SOURCE HOLDER; REF. ANSI N-538 PARA. 3.4.

IN ADDITION; BECAUSE OF THESE LOW LEVELS AND WITH THE INSTRUCTIONS PROVIDED BY RONAN ENGINEERING FOR INSTALLATION AND OPERATION, THE SOURCE HOLDER CAN BE HANDLED SAFELY BY PERSONNEL WITHOUT SPECIFIC RADIATION SAFETY TRAINING.

USERS AND LOCATIONS OF USE VARY THROUGHOUT ALL PROCESS DEPENDENT MANUFACTURERS (ie. CHEMICAL, PLASTICS PLANTS, STEEL MILLS, MINES, ETC.). THE FREQUENCY OF PERSONS BEING NEAR THE SOURCE HOLDER VARIES; BUT IN GENERAL, ONCE THE SOURCE HOLDER IS INSTALLED IT WILL TYPICALLY BE LESS THAN 25 HOURS PER YEAR.

THE RLL-1 SOURCE HOLDER IS NOT USED AS A COMPONENT OF OTHER PRODUCTS. THE EXPECTED USEFUL LIFE OF THE RLL-1 IS AT LEAST FIFTEEN YEARS.

DRAWINGS: SEE ATTACHMENT 1 FIGURES A, B AND C.

LABELING:

AN ETCHED STAINLESS STEEL LABEL AS SHOWN IN ATTACHMENT 1 FIGURE D FOR GENERAL LICENSEES AND FIGURE E FOR SPECIFIC LICENSEES WILL BE ATTACHED TO THE SOURCE HOLDER BY THE USE OF HASDENED STAINLESS STEEL DRIVE SCREWS OR WELDING. DUE TO THE ENVIRONMENTAL CONDITIONS WHERE THE SOURCE HOLDER IS SOMETIMES USED, SILKSCREEN AND OR PAINT WILL NOT SURVIVE. FOR THIS REASON, RONAN IS REQUESTING AN EXEMPTION FROM THE CONVENTIONAL COLOR REQUIREMENTS OF 10 CFR 20.1901.

TESTING OF PROTOTYPES: SEE PHOTOGRAPHS IN ATTACHMENT 1

PROTOTYPE TESTING OF THIS SOURCE HOLDER WAS DONE AT RONAN ENGINEERING FLORENCE, KY. THE UNSHIELDED SOURCE HOLDER PASSED THE FOLLOWING TESTS FOR SAFETY AND INTEGRITY SATISFACTORILY:

a) VIBRATION: 0 THRU 50 CPS AT 0 THRU 1/16" DISPLACEMENT FOR VARYING LENGTHS OF TIME. TOTAL TIME APPROXIMATELY 20 HOURS.

OBSERVATION AT END OF TEST: NO SEPARATION OF WELDMENTS OR MECHANICAL DAMAGE VISIBLE.

- b) TEMPERATURE TESTING WAS DEEMED UNNECESSARY FOR THIS SOURCE HOLDER DUE TO ALL STAINLESS STEEL CONSTRUCTION, NO MOVING PARTS AND THE USE OF SPECIAL FORM SOURCES.
- c) IMPACT: TWO HUNDRED (200) BLOWS WITH A 12 OZ. HAMMER. DROPPED A 1 1/8" DIAMETER STEEL ROD, FROM A HEIGHT OF 40" (1 METER) ONTO THE SOURCE HOLDER.

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OBSERVATIONS AT END OF TEST: THE HAMMER BLOWS MADE ONLY SMALL SURFACE INDENTATIONS. THE STEEL ROD PUT A DENT IN THE OUTER TUBE 0.16 INCHES DEEP. ALL WELDS WERE INTACT. INTEGRITY OF THE SOURCE CONTAINMENT WAS MAINTAINED.

QUALITY CONTROL:

- A) SEALED SOURCE
- 1) EXAMINATION OF VENDOR SOURCE CERTIFICATE FOR PROPER ACTIVITY AND LEAK TEST RESULTS.
- 2) WIPE TEST OF COMPLETE SOURCE HOLDER BEFORE SHIPMENT TO ENSURE LESS THAN 0.005 UCI OF REMOVABLE ACTIVITY. THE APPROVED WIPE TEST EQUIPMENT USED CAN DETECT A MINIMUM 0.001 UCI OF ACTIVITY ON THE WIPE. WIPE TEST RESULTS ARE KEPT ON FILE AT RONAN ENGINEERING.
- **B) RADIATION FIELD INTENSITY SURVEY**
- 1) MEASURE RADIATION FIELD INTENSITY OF COMPLETED SOURCE HOLDER PRIOR TO SHIPMENT TO ASSURE THAT VALUES DO NOT EXCEED 0.5mR/h AT ONE FOOT (30 cm) FROM ANY ACCESSIBLE SURFACE NOR 5mR/h AT 2 INCHES (5cm) FROM ANY SURFACE.
- C) MECHANICAL PARTS AND CONSTRUCTION
- 1) RONAN QUALITY CONTROL PROCEDURES MEET THE APPLICABLE REQUIREMENTS OF ISO-9001.
 - a) VISUAL AND DIMENSIONAL INSPECTION OF PARTS BEFORE AND AFTER ASSEMBLY.
 - b) VISUAL INSPECTION OF MATING SURFACES AND WELDS.
 - c) VERIFICATION OF LABEL FOR PROPER INFORMATION, LOCATION AND ATTACHMENT.
 - d) SHIPPING DOCUMENTATION VERIFICATION.

RADIATION PROFILES: SEE ATTACHMENT 2 FIGURES A, B AND C

INSTALLATION:

FOR GENERAL LICENSEES, IT IS REQUESTED THAT THE USERS OF THE SOURCE HOLDER BE PERMITTED TO INSTALL, STORE AND RELOCATE THE DEVICE IN ACCORDANCE WITH THE INSTALLATION AND OPERATING INSTRUCTIONS PROVIDED BY RONAN. THESE ITEMS ARE COVERED IN THE INSTRUMENT INSTALLATION AND OPERATING MANUAL.

RADIOLOGICAL SAFETY, TRANSFER AND DISPOSAL INSTRUCTIONS:

SEE ATTACHMENTS 3 AND 4 FOR SAFETY, TRANSFER AND DISPOSAL INSTRUCTIONS. PG. 5 OF 10 DOCUMENTATION ACCOMPANYING THE SOURCE HOLDER; WHEN DISTRIBUTED TO GENERAL LICENSEES:

- 1) RADIATION SURVEYS AT TIME OF MANUFACTURE.
- 2) THE INSTALLATION, OPERATION AND RADIATION SAFETY MANUAL IS PROVIDED TO GENERAL LICENSEES WHICH CONTAINS A COPY OF 31.5 OF 10 CFR PART 31 AND AN EXPLANATORY NOTE PER PARAGRAPH 32.51a (b) OF 10 CFR PART 32. (ATTACHMENT 3)
- 3) SPECIAL FORM CERTIFICATE FROM THE MANUFACTURER OF THE SEALED SOURCE CAPSULE.

DOCUMENTATION ACCOMPANYING THE SOURCE HOLDER; WHEN DISTRIBUTED TO SPECIFIC LICENSEES:

- 1) RADIATION SURVEYS AT TIME OF MANUFACTURE.
- 2) INSTALLATION, AND SAFETY INSTRUCTIONS. (ATTACHMENT 4)
- 3) SPECIAL FORM CERTIFICATE FROM THE MANUFACTURER OF THE SEALED SOURCE CAPSULE.

SERVICING AND DISPOSAL:

THE USER WILL BE PROVIDED WITH INSTRUCTIONS TO RETURN THE SOURCE HOLDER BACK TO RONAN FOR SERVICE, REPAIR AND DISPOSAL.

LEAK TESTING:

THE RLL-1 SOURCE HOLDER USES SOURCE CAPSULES THAT CONTAIN LESS THAN 100 MICROCURIES OF CS-137 OR CO-60. EACH SOURCE HAS BEEN INDEPENDENTLY TESTED AND CERTIFIED BY THE MANUFACTURER AS A SPECIAL FORM DEVICE.

DUE TO THE LOW ACTIVITY LEVEL OF THE INDIVIDUAL SOURCES, RONAN ENGINEERING IS REQUESTING THAT THE END USER NOT BE REQUIRED TO LEAK TEST THE DEVICE.

SAFETY ANALYSIS:

DESIGN CRITERIA FOR RADIATION SAFETY:

IT WAS DECIDED THAT THE RADIATION SAFETY CRITERIA FOR THE RLL-1 SOURCE HOLDER WOULD BE A MAXIMUM OF 5 mR/h AT 2 INCHES (5cm) FROM ANY ACCESSIBLE SURFACE, AND 0.50 mR/h AT 12 INCHES (30cm) FROM ANY ACCESSIBLE SURFACE.

THE TIME REQUIRED TO INSTALL THIS SOURCE HOLDER FOR ANY APPLICATION, IS AT MOST, ONE HOUR. THE MAXIMUM EXPOSURE TO THE HANDS AND SKIN, USING SURFACE LEVELS OF 5 mR/h, WOULD BE A

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MAXIMUM OF ONLY 5 mR DURING INSTALLATION, AND AT MOST, 0.50 mR TO THE BODY USING THE 0.5 mR/h AT 12 INCHES EXPOSURE RATE.

THESE DEVICES ONCE INSTALLED REQUIRE NO MAINTENANCE OR SERVICE. THE TIME SPENT BY PERSONNEL WORKING WITHIN 12 INCHES OF THE SOURCE HOLDER WOULD TYPICALLY BE LESS THAN ONE HOUR PER WEEK OR 50 HOURS PER YEAR. THEREFORE THE TOTAL MAXIMUM EXPOSURE FOR 50 HOURS WOULD BE; 50 X 0.50 mR/h = 25 mR/YR. THIS DOSE IS LESS THAN TEN PERCENT (10%) OF THE DOSE LIMIT SPECIFIED IN 10 CFR 20.1201(a).

DESIGN CRITERIA FOR ACCIDENTAL CONDITIONS:

THE DESIGN OF THE RLL-1 PROVIDES FOR ADDITIONAL PROTECTION TO EACH OF THE MULTIPLE SOURCE CAPSULES, WHICH ARE DESIGNED TO MEET SPECIAL FORM. ADDITIONAL ENCAPSULATIONS ARE PROVIDED BY TWO SEPARATE 300 SERIES STAINLESS STEEL TUBES, TO PROVIDE ASSURANCE THAT NONE OF THE RADIOACTIVE MATERIAL WILL BE RELEASED UNDER ACCIDENTAL CONDITIONS OF FIRE OR EXPLOSION.

THE RLL-1 SOURCE HOLDER IS ALSO WELDED TO THE SHIELD, WHICH IS CONSTRUCTED OF STEEL, WITH ENCAPSULATED LEAD OR TUNGSTEN, AS REQUIRED, TO REDUCE THE RADIATION LEVELS ABOUT THE APPLICATION TO LESS THAN 5 mR/h SURFACE AND 0.50 mR/h AT 12 INCHES. HOWEVER; EVEN IF THE SHIELD SEPARATED OR FAILED IN AN ACCIDENT, OR EXPLOSION, THE MAXIMUM EXPOSURES FROM THE UNSHIELDED RLL-1 SOURCE HOLDER WOULD BE NO MORE THAN 100 mR/h SURFACE AND 5.0 mR/h AT 12 INCHES, WITH THE MAXIMUM ACTIVITY OF 900 MICROCURIES OF CS-137 OR 200 MICROCURIES OF CO-60 IN THE SOURCE HOLDER. THIS IS CONFIRMED BY UNSHIELDED RLL-1 SOURCE HOLDER CALCULATIONS:

CS-137; EQUATION 1

 $R(mR/h) = \frac{0.900mCi \times 500}{(0.375 + d) (IN)}$

NOTE: (0.375) IS THE RADIUS OF THE DEVICE

AT d = 2" (SURFACE), SOLVING EQUATION 1

 $.9 \times 500$ R(mR/h) = ----- = 80 mR/h @ SURFACE (2.375)

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AT d = 12", SOLVING EQUATION 1

R(mR/h) = ----- = 2.9 mR/h @ 12" $\frac{2}{12.375}$

CO-60; EQUATION 2 0.200mCi X 2000 R(mR/H) = ----- $(0.375 + d)^2$ (in) NOTE: (0.375) IS THE RADIUS OF THE DEVICE AT d = 2" (SURFACE), SOLVING EQUATION 2 .200 X 2000 R(mR/h) = $= 70 \text{ mR/h} \otimes \text{SURFACE}$ 2 2.375 AT d = 12", SOLVING EQUATION 2 .200 X 2000 ----- = 2.6 mR/h @ 12" R(mR/h) =2

12.375

IN ORDER FOR A PERSON TO RECEIVE AN EXTERNAL RADIATION DOSE IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN TABLE OF 10 CFR 32.24, IT WOULD TAKE THE FOLLOWING EXPOSURE TIME:

a) WHOLE BODY: LIMIT 15 REM; RADIATION =3.5 mR/h AT 12"

15 REM = 3.5mR/h X y

y = 4,286 HOURS

THIS IS ALMOST IMPOSSIBLE TO OCCUR

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b) HANDS/FOREARMS: LIMIT = 200 REM

SURFACE CONTACT DOSE RATE = 100 mR/h

200 R = 100 mR/h X y

y = 2000 HOURS

THIS IS ALMOST IMPOSSIBLE TO OCCUR

c) OTHER ORGANS: 50 REM; RADIATION = 3.5 mR/h

50 REMS = 3.5 mR/h X y

y = 14,286 HOURS

THIS IS IMPOSSIBLE TO OCCUR

FROM THIS ANALYSIS EVEN IN AN ACCIDENT WHERE THE SHIELD WAS MADE INEFFECTIVE, THE DOSE LEVELS FROM THE UNSHIELDED SOURCE HOLDER ARE SUCH THAT IT WOULD BE VIRTUALLY IMPOSSIBLE FOR A PERSON TO INCUR AN EXTERNAL RADIATION DOSE IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN 10 CFR 32.24.

RADIATION SURVEYS: SEE ATTACHMENT 2 FIGURES A THRU C

DENSITY/POINT LEVEL GAGE: WORST CASE 2" PIPE, 900 MICROCURIE CS-137 FIGURE A OR 200 MICROCURIE CO-60 FIGURE A(i)

CONTINUOUS LEVEL: WORST CASE: 900 MICROCURIE CS-137 FIGURE B OR 200 MICROCURIE CO-60 FIGURE B(i) ON A 2" PIPE

WEIGH SCALE GAGE: WORST CASE: 12" ACTIVE LENGTH, 900 MICROCURIES CS-137 FIGURE C OR 200 MICROCURIE CO-60 FIGURE C(i); 12" THROAT DEPTH.

SUMMARY:

ONE CAN SEE FROM THE WORST CASE SURVEYS THAT THE RADIATION LEVELS WILL NOT EXCEED THE CRITERIA OF 5 mR/h SURFACE OR 0.5 mR/h AT 12".

SHIPPING SHIELD:

WHEN THE RADIATION BEAM AT THE EXIT PORT EXCEEDS 5mR/h ON THE SURFACE; EACH RLL-1 SOURCE HOLDER IS SHIPPED WITH A SHIPPING SHIELD COVERING THE RADIATION BEAM EXIT PORT (WHERE THE ACTIVE BEAM EMANATES FROM). THE SHIELD REDUCES THE MAXIMUM RADIATION ON THIS SIDE OF THE SOURCE HOLDER TO THE SAME LEVELS AS ON ANY ACCESSIBLE SURFACE, i.e., 5mR/h SURFACE (2 INCHES OR 5 cm) OR

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0.5mR/h AT (12 INCHES OR 30cm). THIS SHIELD IS REMOVED FROM THE EXIT PORT DURING INSTALLATION ON THE APPLICATION (DENSITY, LEVEL,ETC.) AND ATTACHED TO THE BACK SURFACE OF THE SHIELD AS DIRECTED IN THE INSTALLATION INSTRUCTIONS PROVIDED BY RONAN.

THE USER WILL BE INSTRUCTED TO USE THE SHIPPING SHIELD WHENEVER THE RLL-1 SOURCE HOLDER IS TO BE DISMOUNTED OR REMOVED FROM THE APPLICATION FOR STORAGE, TRANSFER OR RELOCATION.

WE TRUST THAT THIS INFORMATION IS COMPLETE AND ADEQUATE FOR YOUR SAFETY EVALUATION OF THE RLL-1 SOURCE HOLDER.

SINCERELY;

CRAIG A. CARIS QUALITY MANAGER

ATTACHMENT 1

DRAWINGS

OUTLINE RLL-1 SOURCE HOLDER WITH SHIELD DETAIL RLL-1 SOURCE HOLDER DETAIL RLL-1 SOURCE HOLDER WITH END PLATE GENERAL LICENSE / RADIOACTIVE MATERIAL LABEL RADIATION CAUTION LABEL - SPECIFIC LICENSE CONFIGURATION - DENSITY APPLICATION CONFIGURATION - LEVEL APPLICATION CONFIGURATION - WEIGH APPLICATION

PHOTOGRAPHS - PROTOTYPE / DOT TESTING DOT 7A TYPE A TEST CERTIFICATION DROP TEST

RLL-1 SOURCE HOLDER

VIBRATION TEST





IMPACT TEST STEEL ROD

IMPACT TEST 12 OZ HAMMER

RONAN TYPE A PACKAGING TEST

DATE 7/10/98

MODEL RLL-1

TESTING CONDUCTED IN ACCORDANCE WITH 49 CFR CH. 1 SECT. 173.465

b) WATER SPRAY TEST

CONTAINER CONSTRUCTION: CONTAINER IS CONSTRUCTED OF 3/4" OD X 0.065 WALL STAINLESS STEEL TUBING. THE SOURCE ROD IS 1/4" OD X .035 WALL S.S. TUBING CENTERED IN THE OUTER TUBE. STAINLESS STEEL PLUGS ARE CONTINUOUSLY WELDED TO THE ENDS OF THE OUTER TUBE.

TEST:

WATER SPRAY TEST STARTED 7/10/98 AT 9:10 A.M.; FINISHED AT 10:10 A.M.

OBSERVATION:

THE WATER SPRAY TEST SHOWED THAT NO MOISTURE ENTERED THE CONTAINER OR SOAKED INTO THE CONTAINER MATERIAL. CONCLUSION: WATER SPRAY TEST IS NOT APPLICABLE TO THIS DESIGN AND NEED NOT BE REPEATED BETWEEN TESTS PER SUBPARAGRAPH (b).

(c) FREE DROP TEST

TEST:

PLACED CONTAINER ON FLAT SURFACE 48 INCHES ABOVE HORIZONTAL CONCRETE TARGET AREA.

LET CONTAINER FALL ONTO TARGET AREA, IMPACTING ON THE SIDE OF THE OUTER TUBE.

OBSERVATION:

NO DAMAGE WAS OBSERVED.

(d) COMPRESSION TEST

CALCULATIONS: ENGINEERING ANALYSIS SHOWS A 7589:1 SAFETY FACTOR

CONTAINER WEIGHT 3.2 LBS.; SURFACE AREA 2.88 SO. IN.

APPLIED LOAD = 16 LBS. (WEIGHT X 5)

WORKING PRESSURE = 5.55 LB. PER SQ. IN.

EXTERNAL COLLAPSING PRESSURE OF CYLINDER WITH SIMPLY SUPPORTED ENDS. WC = KE $\begin{pmatrix} t \\ - \end{pmatrix}^3$

D ENDS. WC = KE
$$\begin{pmatrix} - \\ D \end{pmatrix}$$

E = YOUNGS MODULUS OF ELASTICITY = 28.5 X 10

D = OUTSIDE DIA. = .75 IN t = WALL THICKNESS = .065

L = LENGTH = 48 IN.

K = NUMERICAL COEFFICIENT BASED ON L/D AND D/t RATIOS

Wc = 1.0 X 28.5 x 10 $\begin{pmatrix} .065 \\ ---- \\ .75 \end{pmatrix}$ 3 = 18552 LBS/IN

REFERENCE: MARK'S HANDBOOK FOR MECHANICAL ENGINEERS AVALLONE AND BAUMEISTER 9th EDITION McGRAW-HILL

(e) PENETRATION TEST

TEST:

PLACED CONTAINER ON FLAT CONCRETE SURFACE. USED 2" DIA. TUBE AS GUIDE, PLACED AGAINST THE OUTER TUBE AND HELD PERPENDICULAR TO THE CONTAINER SURFACE. DROPPED 1.25" DIA. STEEL BAR WITH HEMISPHERICAL END THROUGH TUBING FROM A HEIGHT OF 40" ABOVE THE CONTAINER, IMPACTING ON THE OUTER TUBE.

OBSERVATION:

THE STEEL BAR DENTED THE OUTER TUBE 0.16" DEEP. NO OTHER DAMAGE WAS OBSERVED.

I CERTIFY THAT THE AFOREMENTIONED TESTS WERE CONDUCTED BY RONAN ENGINEERING, MEASUREMENTS DIVISION, FLORENCE, KY. AND THAT EACH TEST WAS CONDUCTED AND OBSERVED AS STATED IN THIS REPORT.

THE DESIGN EVALUATION AND TEST RESULTS DEMONSTRATE THAT THE CONTAINER DESIGN AND CONSTRUCTION MEET THE D.O.T. REQUIREMENTS FOR TRANSPORT OF SPECIAL FORM MATERIALS. CONTAINERS OF THIS DESIGN AND CONSTRUCTION ARE HEREBY APPROVED TO TRANSPORT SPECIAL FORM MATERIALS.

CRAIG A. CARIS

QUALITY MANAGER

ATTACHMENT 2

-a

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ISO DISTANCE CURVES (RADIATION SURVEYS)

DENSITY APPLICATION	CS-137	&	CO-60
LEVEL APPLICATION	CS-137	&	CO-60
WEIGHT APPLICATION	CS-137	&	CO-60

MANUFACTURERS SEALED SOURCE REGISTRY AND IAEA CERTIFICATE

AMENDED IN ITS ENTIRETY. AUGUST 30, 1994 NO: CA406S118S DATE: April 23, 1975

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SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

MODEL:

PHI-XXX GFS Series

(Formerly GFS Series)

XXX Represents Radionuclide Mass Number

MANUFACTURER/DISTRIBUTOR:

Isotope Products Laboratories 1800 North Keystone Street Burbank, California 91504

(818) 843-7000

ISOTOPE:	(a) Sodium	22 MAXIMUM ACTIVITY	(a)	5 millicuries
	(b) Cobalt 5	57 .	(b)	300 millicuries
	(c). Cobalt 5	8	(c)	300 millicuries
	(d) Cobelt 6	60	(d)	10 millicuries
	(e) Germani	ium 68	(e)	50 millicuries
	(f) Strontiu	m 90	(f)	125 millicuries
	(g) Rutherin	um 106	(g)	50 millicuries
	(h) Barium	133	(h)	100 millicuries
	(i) Cesium	137	(i)	300 millicuries
	(j) Lanthani	ide Series	Ö	300 millicuries
	(Ce. Pr.	Sm, Eu. Gd, Yb, Tm)	•/	· · · · · · · · · · · · · · · · · · ·
:	(k) Actinide	Series	(k)	300 or 30 millicuries
·	(Ac. Th.	Pa,U. Pu, Am, Cm)	~ ~ ~	(see description)
	(l) Radium	226	(i)	50 millicuries

LEAK TEST FREQUENCY: Six months

PRINCIPAL USE: X-Ray Fluorescence (U).

CUSTOM SOURCE: ____YES X__NO

AMENDED IN ITS ENTIRETY AUGUST 30, 1994 DATE: April 23, 1975

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SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

DESCRIPTION:

NO: CA406S118S

The GFS Series is represented by IPL Capsule Drawings A3201, A3202, A3203, A3224-01, A3224-02, A3224-03, A3224-11, A3224-12, A3224-13, and A3807. These sources are singly encapsulated and constructed of type 304 or 304L stainless steel or titanium with a minimum wall thickness of 0.010" and a minimum window thickness of 0.002". Several sizes are available: (1) 0.20" long x 0.312" diameter, (2) 0.394" long x 0.118", 0.157", or 0.275" diameter, (3) 0.197" long x 0.118" diameter, or (4) 0.40" long x 0.12" diameter. Some designs have internal tungsten shielding. Seals are effected by fusion welding.

The chemical form of the active elements in the PHI-XXX GFS scries are Chlorides, Nitrates, or Oxides in ceramic, Oxides in Gold or Aluminum, or metal plated onto substrate.

The Actinide loading depends on the chemical form and window thickness. The 300 mCi limit applies to oxides in ceramic with the 0.010" windows, and the 30 mCi limit applies to the plated oxides and 0.002" window.

These sources have been designated as "Special Form" and have been issued Special Form Certificate Number USA/0357/S.

LABELING:

The source is engraved with IPL, the nuclide, nominal activity, and serial number.

DIAGRAM:

See pages 8 through 12 for Drawings of Capsules A3201, A3202, A3203, A3224-XX, and A3807.

CONDITIONS OF NORMAL USE:

These sources are designed for use in source holders for the purpose of gauging or X-Ray fluorescence.

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SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

PROTOTYPE TESTING:

NO: CA406S118S

Prototype sources have undergone testing per ANSI N542-1977 and meet or exceed the following classifications:

<u>Capsule</u>	ANSI N542-1977 Classification	Recommended Usage
A3201	77C66545	Gamma Gauging
A3202	77C66545	Gamma Gauging
A3203	⁻ 77C66545	Gamma Gauging
A3224	·/7C66444	Gamma Gauging
A3807	11C66444	Gamma Gauging

EXTERNAL RADIATION LEVELS:

The radiation level of the source will vary with the contained radionuclide and the activity level. Listed below are radiation levels in R/hr. Data has been taken where available from references 9 and 10. For nuclides not listed in the referenced tables, measurements were taken at 30 cm with an ion chamber type survey meter and radiation levels were calculated at 5 and 100 cm using the inverse square law (for gamma or X-ray radiation), and calculations for Beta radiation were performed according to the method described in reference 12.

	· · ·		Distance from source	2
Nuclide	Activity	<u>5 cm</u>	<u>30 cm</u>	100 cm
(a) Na-22	5 mCi	2.4	0.067	0.006
(b) Co-57	300 mCi	10.8	0.3	0.027
(c) Co-58	300 mCi	66	1.83	0.165
(d) Co-60	10 mCi	5.28	0.147	0.0132
(e) Gc-68	50 mCi	10,5	0,29	0.026

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SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

EXTERNAL RADIATION LEVELS (Continued):

		1	Distance from source		
Nuclide	Activity	<u>5 cm</u>	<u>30 cm</u>	<u>100 cm</u>	
(f) Sr-90	125 mCi	2975	66	3.0	
(g) Ru-106	50 mCi	3.4	.0.094	0.0085	
(h) Ba-133	100 mCi	9.6	0.267	0.024	
(i) Cs-137	300 mCi	39.6	1.1	0.099	
(j) Lanthanides	300 mCi	74.4	2.07	0.186	(from Eu-154)
(k) Actinides	300 mCi	6700	195	17.5	(from Th-228)
(l) Ra-226	50 mCi	2190	60.8	5,46	

OUALITY ASSURANCE AND CONTROL:

<u>Program</u>: The IPL Quality Assurance Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10CFR Part 50 (B) and meets the requirements of ISO 9001. The program covers drawing control, purchasing, training, calibration records, source numbering, incoming raw materials, assay quality control, leak testing, document control, confirming orders, and pre-production design review.

Activity: Held to ± 15% of nominal activity

<u>Assay procedures:</u> A Calibrated Ionization Chamber is used to measure the activity of the source. For actinides, the content is measured by liquid scintillation counting of an aliquot of starting material.

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PAGE: 5 OF 12

SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

OUALITY ASSURANCE AND CONTROL (Continued):

Radiopurity determination: Determined by gamma or alpha spectrometry of the source or the radionuclide batch.

<u>Leak test procedures</u>: Sources are either leak tested according to the "Immersion With Boiling Test" taken from ANSI N542 1977 Appendix A A2.1.3, or the immersion test from Appendix to ANSI N44.2-1973 "American National Standard for Leak Testing Radioactive Brachytherapy Sources." Criteria for acceptance are:

1.0 nCi removable beta/gamma0.1 nCi removable alpha

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE

- a. <u>Distribution</u>: These sources shall be distributed to specific licensees of the NRC or Agreement States.
- b. <u>Leak Test</u>: Beta and/or gamma emitting sources containing radioactive material in excess of 100 microcuries, and alpha and/or neutron emitting sources containing radioactive material in excess of 10 microcuries shall be tested at intervals not greater than six months. Such tests must be capable of detecting 0.005 microcuries of removable radioactivity, and be performed by specific licensees of the NRC or Agreement States.
- c. <u>Use</u>: These sources are intended to be used by trained personnel in a laboratory environment for checking or calibrating nuclear instrumentation, or to be permanently installed in devices. These sources should not be subjected to conditions exceeding their respective ANSI N542-1977 ratings.
- d. <u>Handling</u>: Remote handling tools and localized shielding should be used.
- e. <u>Storage</u>: Store in a clean, dry area. Shielding should be provided as necessary.
- f. <u>Cleaning</u>: Sources may be cleaned with alcohol or water with a mild detergent.

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AMENDED IN ITS ENTIRETY, AUGUST 30, 1994 NO: CA406S118S DATE: April 23, 1975

PAGE: 6 OF 12

SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Continued)

- g. <u>Disposal</u>: Disposal of decayed or otherwise unusable sources must be made via the user's authorized radioactivity disposal method.
- h. This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, we find this series of sources to be acceptable for licensing for the proposed uses in gauging and X-ray Fluorescence devices.

REFERENCES:

- 1) Isotope Products Laboratories letters with attachments dated February 11, March 11, and April 10, 1975
- 2) Isotope Products Laboratories letters with attachments dated January 9, January 18, and February 18, 1982.
- 3) NBS Handbook No. 126, ANSI N.542, "Sealed Radioactive Sources, Classification", 1977.
- 4) Isotope Products Laboratories letter dated March 26, 1985 with attached Special Form Certificate No. USA/0357/S.
- 5) Isotope Products Laboratories letter with attachments dated February 6, 1990.
- 6) Isotope Products Laboratories letter with attachments dated April 20, 1990.
- 7) Isotope Products Laboratories letter with attachments dated July 21, 1992.
- 8) Appendix to ANSI N44.2-1973 "American National Standard for Leak Testing Radioactive Brachytherapy Sources."

AMENDED IN ITS ENTIRETY. AUGUST 30, 1994 DATE: April 23, 1975

PAGE: 7 OF 12

SEALED SOURCE TYPE: Gauging and X-Ray Fluorescence

REFERENCES: (Continued)

NQ: CA406S118S

- 9) "Radiological Health Handbook", page 131, 1970.
- 10) "The Health Physics and Radiological Health Handbook", Table 13.14 "Beta Ray Doso Rates for an Isotropic Source in Air of Density 1.205mg/cm³", Revised Edition, Edited by Bernard Shleien, 1992.
- 11) Isotope Products Laboratories Quality Assurance Manual.
- 12) Isotope Products Laboratories letters with attachments, dated January 7, May 20, August 8, and August 12, 1994.

TTEN BY DATE **REVIEWED BY:** DATE

ISSUING AGENCY:

California Department of Health Services



US Departitikani

c00 Saventh Street, S.W.
Washington, D.C. 20590

Research and IAEA CERTIFICATE OF COMPETENT AUTHORITY Special Programs SPECIAL FORM RADIOACTIVE MATERIAL Administration CERTIFICATE NUMBER USA/0516/9, REVISION 0

This certifies that the sources described below have demonstrated their ability to meet the regulatory requirements for special form radioactive material as prescribed in the regulations of the International Atomic Energy Agency¹ and United States of America² for the transport of radioactive materials.

- Source Identification Isotope Products Laboratories (IPL) Model Nos. A3224-01, A3224-02, A3224-03, A3224-11, A3224-12, A3224-13, and A3807 source capsules.
- 2. Source Description The sources described by this certificate are wolded, single encapsulations constructed of Type 304 stainless steel, 304L stainless steel or titanium, and which have a 0.25 mm (0.010") thick integral window at one end. Source capsules measure 3.0 mm (0.118") in diameter x 10 mm (0.394") long, 7 mm (0.275") in diameter x 10 mm (0.394") long, or 3.0 mm (0.118") in diameter x 10.2 mm (0.4") long. Source capsules shall be constructed in accordance with the attached IPL drawing nos. 3224 or A3807.
- 3. <u>Radioactive Contents</u> The sources described by this certificate are authorized to contain any one of the following radionuclides in the chemical form identified and limited to the activity shown.

Radionuclide	Form	<u>Activity</u>
NA-22	NaCl in gold or ceramic	185 MBq (5 mC1)
Co-57	Co metal plated on Ni foil or CoO in ceramic	11,100 MBg (300 mC1)
Co-58	Co metal plated on Ni foil or CoO in ceramic	11,100 MBq (300 mCi)

¹ "Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1985 Edition, As Amended 1990," published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

1 march AD Code of Federal Regulations, Parch 100 - 199,

(- 3 -)

CERTIFICATE UBA/0516/S. REVISION 0

his certificate is issued in accordance with paragraph 703 of the IAEA Regulations and Section 173.476 of Title 49 of the Code of Federal Regulations, in response to the petition and information dated February 5, 1996 submitted by Isotope Products Jaboratories, Burbank, CA and in consideration of other information on file in this Office.

certified by: APR - 5 1996 (DATE) Alan I. Roberts Associate Administrator for Hazardous Materials Safety

Revision 0 - Issued in response to Isotope Products Laboratories request to break USA/0357/S into four separate certificates.

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CERTIFICATE USA/0516/8, REVISION 0

Radionuclide	Form	Activity
Co-60	Co metal plated on Ni foil or CoO in ceramic	370 MBq (10 mCi)
Ge-68	GeO, in silver	1850 MBg (50 mC1)
Sr-90	SrTiO, in Ag or SrO2 in ceramic	4625 MBg (125 mC1)
Ru-106	Ru metal plated on Pt	1850 MBq (50 mCi)
Cs-137	CsCl in gold or Cs in ceramic	11,100 MBg (300 mCi)
Ba-133	BaSO4 in ceramic or BaCl2 in ceramic	3700 MBg (100 mC1)
Lanthanides	Oxides plated on Pt, in ceramic, or aluminum	11,100 MBq (300 mCi)
Actinides	Oxides in ceramic or aluminum	11,110 MBg (300 mC1)
* (Teotones	of Co. Pr. Sm. Eu. Yh.	and Tm only)

** (Isotopes of Ac, Th, Pa, U, Pu, Am, and Cm only)

4. Records of Quality Assurance activities required by Paragraph 209 of the IAEA regulations¹ shall be maintained and made available to authorized officials for at least three years after the last shipment authorized by this certificate. Consignors and consignees in the United States exporting or importing shipments under this certificate shall satisfy the requirements of Subpart H of 10 CFR 71.

5. Expiration Date - This certificate expires on April 1, 2001.

Cesium-137

Gamma sources

Sources contain the radionuclide as a pellet of cesium ceramic.

Encapsulation is in welded stainless steel. Sources up to 300mCi, 11-1GBq are supplied with single X.7 or double encapsulation X.8. Higher activity sources are double encapsulated X.9.

Nominal air kerma rate at 1 metre	Nominal equivalent activity*	Single encapsulation Code	Double encapsulation Code
µGy/hr	mCi	(X.7)	(X.8)
2.88	1	CDC.701	CDC.801
5.76	2	CDC.702	CDC.802
8.64	3	CDC.703	CDC.803
14-4	5	CDC.704	CDC.804
28.8	10	CDC.705	CDC.805
43.2	15	CDC.70550	CDC.80550
57.6	20	CDC.706	CDC.806
72·0	25	CDC.70650	CDC.80650
86.4	30	CDC.707	CDC.807
144	50	CDC.708	CDC.808
288	100	CDC.709	CDC.809
576	200	CDC.710	CDC.810
864	300	CDC.711	CDC.811

*Tolerance: Single encapsulated sources – 5%, +20% Double encapsulated sources – 10%, +15% For definition of equivalent activity, see page E1.

Recommended working life: 15 years

Nominal air kerma rate at 1 metre mGy/hr	Nominal equivalent activity* mCi	Double encapsulation Code (X.9)
1.44	500	CDC.90
2.88	1000	CDC.91
5.76	2000	CDC.92
8.64	3000	CDC.93
11.52	4000	CDC.94
14-40	5000	CDL.95

*Tolerance - 10%, +15%

For definition of equivalent activity, see page E1.

Recommended working life: 15 years

Quality Control

Wipe test A Bubble test D Immersion test M

Calibrated sources

Cesium-137 sources, 3mCi-3Ci, 0.11GBq-111GBq, can be supplied calibrated with measured radiation output code H50. Calibration accuracy: $\pm 5\%$ overall uncertainty. Further details on request.



Safety performance testing

Capsule ANSI/ISO classification	IAEA special form DNS Model No.
X7	GB/23/S CDC 700
X8	GB/24/S CDC 800



Quality control: Leakage and Contamination tests, see page D1 A Test Report is supplied with each source or batch of sources.

Safety performance testing, see page F1

Dimensions in mm

ATTACHMENT 3

INSTALLATION, AND RADIATION SAFETY MANUAL GENERAL LICENSEES

INSTALLATION, OPERATION AND RADIATION SAFETY MANUAL

RONAN LOW LEVEL SERIES (RLL-1) DEVICES

GENERAL LICENSE - THE RONAN LOW LEVEL SERIES OF DEVICES ARE MANUFACTURED BY RONAN ENGINEERING, FLORENCE, KENTUCKY. THE DEVICES HAVE BEEN TESTED AND CERTIFIED AS A DOT 7A TYPE A PACKAGE AND ARE APPROVED FOR DISTRIBUTION TO GENERAL LICENSEES. REGULATIONS PERTAINING TO THESE DEVICES ARE FOUND IN TITLE 10 CFR PARA. 31.5, AND ARE ENCLOSED IN THIS MANUAL. IT IS THE OBLIGATION OF THE USER TO MAINTAIN A CURRENT COPY OF THE REGULATIONS OR AGREEMENT STATE REGULATIONS EQUIVALENT TO 10 CFR 31.5. A LISTING (CURRENT AT TIME OF PRINTING) OF NRC REGIONAL OFFICES AND AGREEMENT STATE OFFICE LOCATIONS ARE INCLUDED IN THIS MANUAL; UPDATED INFORMATION MAY BE OBTAINED FROM THE NRC WEB PAGE AT NRC.GOV.COM.

THE DEVICE, IF INSTALLED IN ACCORDANCE WITH THE MANUFACTURERS INSTRUCTIONS AS PROVIDED IN ATTACHMENT 1, AND WITH CERTAIN MINIMAL PRECAUTIONS CAN BE SAFELY USED FOR THE SPECIFIC PURPOSES OF MEASURING DENSITY, LEVEL OR WEIGHT, BY PERSONS NOT TRAINED IN RADIATION PROTECTION. THE DEVICE IS INTENDED ONLY TO BE USED FOR THESE PURPOSES. THE GENERAL LICENSEE IS REQUIRED TO COMPLY WITH THE REGULATIONS OF 10 CFR PART 31, OR THE AGREEMENT STATE REGULATIONS EQUIVALENT TO PART 31, EVEN THOUGH NO APPLICATION FOR LICENSE OR SPECIAL DOCUMENTATION IS ISSUED.

RONAN ISSUES A REPORT OR REGISTRATION, TO THE NRC OR THE AGREEMENT STATE IN WHICH THE LICENSEE IS LOCATED, OF ALL TRANSFERS OF THESE DEVICES TO GENERAL LICENSEES WITH THEIR NAMES AND ADDRESSES.

NRC OR STATE INSPECTION

EACH LICENSEE, WHETHER A SPECIFIC OR A GENERAL LICENSEE, IS SUBJECT TO INSPECTION BY THE NRC OR AGREEMENT STATE. HE MUST AFFORD THE NRC OR AGREEMENT STATE, AT ALL REASONABLE TIMES, OPPORTUNITY TO INSPECT RADIOACTIVE MATERIAL UNDER HIS CONTROL.

RADIATION PROTECTION

THE RONAN LOW LEVEL SERIES OF SOURCE HOLDERS UTILIZE SOURCE MATERIAL WITH A MAXIMUM ACTIVITY OF 900 MICROCURIES OF CESIUM-137, OR 200 MICROCURIES OF COBALT-60 PER SOURCE HOLDER. WITH A MAXIMUM OF 90 MICROCURIES PER SOURCE CAPSULE. THE CONSTRUCTION OF EACH SOURCE IS CERTIFIED AS SPECIAL FORM, AS THE EXTERIOR OF EACH CAPSULE IS MADE FROM STAINLESS STEEL AND THE RADIATION MATERIAL IS TOTALLY ENCAPSULATED BY HELI-ARC WELDING. THESE SPECIAL FORM QUANTITIES ARE THEN DISTRIBUTED INSIDE THE RONAN LOW LEVEL DEVICE WHICH IS MADE FROM STAINLESS STEEL AND WELDED CLOSED AT BOTH ENDS PRIOR TO BEING INSERTED INTO ITS RADIATION SHIELD.

THE GENERAL LICENSEE IS NOT PERMITTED TO REPAIR, MODIFY OR OTHERWISE TAMPER WITH THE DEVICE OR ITS SHIELDING.

REV. 2 12/23/98

THE HIGH INTEGRITY, AND THE LOW SOURCE QUANTITY, PERMITS THE GENERAL LICENSEE TO COMMISSION THE DEVICE WITHOUT WIPE TESTING OR TESTING OF ANY KIND AS PER 10 CFR PART 31.5(c)(2)(ii).

UNDER ORDINARY AND ACCIDENTAL CONDITIONS, IT IS UNLIKELY THAT ANY PERSON WOULD RECEIVE AN EXTERNAL DOSE IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN IV OF THE TABLE IN 10 CFR PART 32.24. ALSO IT CAN BE DEMONSTRATED THAT IF THE DEVICE IS USED AS INTENDED IN THE MANUFACTURERS (RONAN) INSTRUCTIONS, A CALENDER DOSE IN EXCESS OF TEN PERCENT (10%) OF THE LIMITS SPECIFIED IN 10 CFR PART 20.1201(a) IS UNLIKELY.

IN CASE OF SUSPECTED DAMAGE, RONAN ENGINEERING SHOULD BE CONSULTED FOR INSTRUCTIONS TO RETURN THE DEVICE FOR REPAIR OR DISPOSAL.

RADIATION DOSE ESTIMATE TO PERSONNEL USING THE RONAN LOW LEVEL SERIES OF DEVICES:

ISO DISTANCE CURVES ARE PROVIDED IN DRAWINGS B-16305 AND B-16308 FOR DENSITY/POINT LEVEL GAGES, B-16306 AND C-16309 FOR CONTINUOUS LEVEL GAGES AND C-16307 AND C-16310 FOR WEIGH GAGES. THE MAXIMUM EXPOSURE AT ONE FOOT FROM THE DEVICE IS LESS THAN 0.5 mR/h. MOST OF THESE DEVICES ONLY REQUIRE, AS A CONSERVATIVE ESTIMATE, LESS THAN ONE HOUR OF HANDLING TO INSTALL. BASED ON THESE LOW EMISSION LEVELS, AND THE SHORT DEVIATION TIME SPENT INSTALLING AND WORKING IN THE VICINITY OF THE DEVICE, IT CAN BE SAFELY ASSUMED THAT THE WORKING PERSONNEL WILL RECEIVE EXPOSURES CONSIDERABLY LESS THAN 10 PERCENT (10%) OF THE DOSE LIMITS IN COLUMN IV OF PART 32.24 FOR THE APPROPRIATE ORGANS, AND LESS THAN TEN PERCENT (10%) OF THE DOSE STANDARDS IN PART 20.1201(a).

LABELING:

THE STAINLESS STEEL "CAUTION - RADIOACTIVE MATERIAL" LABEL MUST NOT BE REMOVED PER 10 CFR 31.5.

TRANSFER:

THE GENERAL LICENSEE SHALL NOT TRANSFER OWNERSHIP OF THE DEVICE EXCEPT AS SPECIFIED IN 10 CFR 31.5.

DISPOSAL:

THE DEVICE MUST BE RETURNED TO RONAN ENGINEERING OR A SPECIAL LICENSED RADIOACTIVE MATERIAL BROKER, PURSUANT TO PARTS 30 AND 32 OF 10 CFR, FOR DISPOSAL. RONAN ENGINEERING WILL PROVIDE PACKAGING INSTRUCTIONS UPON REQUEST.

ATTACHMENTS:

INSTALLATION INSTRUCTIONS FOR THE RLL-1 DEVICE
COPY OF TITLE 10 CFR PARA. 31.5
NRC REGIONAL OFFICES AND AGREEMENT STATE OFFICES
ISO DISTANCE CURVES REV. 2 12/23/98



\$31.5 Certain measuring, gauging or controlling devices.²

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to §32.51 of this chapter or in accordance with the specifications contained in a specific license issued by an Agreement State which authorizes distribution of the devices to persons generally licensed by the Agreement State.

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:

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(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) In accordance with the instructions provided by the labels; or

(ii) By a person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage or radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the

²Persons possessing byproduct material in devices under the general license in §31.5 before Jan. 15, 1975, may continue to possess, use or transfer that material in accordance with the requirements of §31.5 in effect on Jan. 14, 1975.

sealed source is transferred or disposed of.

(iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.905 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device and, within 30 days, furnish to the Administrator of the appropriate Nuclear Regulatory Commission, Regional Office listed in appendix D of part 20 of this chapter, a report containing a brief description of the event and the remedial action taken:

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with part 110 of this chapter;

(8) Except as provided in paragraph (c)(9) of this section, shall transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(9) Shall transfer the device to another general licensee only:

(i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. Washington, DC 20555, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Commission and the transferee; or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21, of this chapter.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

[39 FR 43532, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 40 FR 14085, Mar. 28, 1975; 42 FR 25721, May 19, 1977; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 53 FR 19246, May 27, 1988; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993] LISTING OF NRC REGIONAL OFFICES AND STATE PROGRAM DIRECTORY

REGION I

US NUCLEAR REGULATORY COMMISSION 475 ALLENDALE ROAD KING OF PRUSSIA, PA. 19406-1415 610-337-5000

REGION II

US NUCLEAR REGULATORY COMMISSION REGION II ATLANTA FEDERAL CENTER (AFC) TOWER 61 FORSYTH STREET, NW, SUITE 23T85 ATLANTA, GA. 30303 404-562-4400

REGION III

US NUCLEAR REGULATORY COMMISSION 801 WARRENVILLE ROAD LISLE, IL. 60532-4351 630-829-9500

REGION IV

US NUCLEAR REGULATORY COMMISSION HARRIS TOWER 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX. 76011-8064 817-860-8100