December 16, 1994

MEMORANDUM TO: Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research

FROM: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

SUBJECT: REQUEST FOR REEVALUATION OF THE SAFETY BASE FOR EXEMPT DISTRIBUTION OF SMALL QUANTITIES AND EXEMPT CONCENTRATIONS OF BYPRODUCT MATERIALS

Section 30.18 of 10 CFR Part 30, currently allows a member of the general public to receive sealed and unsealed radioactive materials without further NRC regulatory control provided the activity of an individual quantity of radioactive material does not exceed the exempt quantity set forth in § 30.71 Schedule B of 10 CFR Part 30 and the materials are authorized for distribution pursuant to sections 32.18-32.20 of 10 CFR Part 32.

When the Commission published the proposed rule (33 FR 1114, August 10, 1968), dealing, in part, with § 30.18, it stated:

> The proposed amendment to 10 CFR Part 30 would add a new § 30.71, Schedule B, of exempt quantities . . . Two basic criteria were used in deriving the quantities. Since inhalation is considered the most likely route of entry into the body, the quantity that would be inhaled by a standard man exposed for 1 year at the highest average concentration permitted in air (by 10 CFR Part 20) for members of the general public was computed. If the radioisotope emits gamma radiation, the quantity that, from a point source, would produce a radiation level of 1 milliroentgen per hour at a distance of 10 centimeters was also computed. The smaller of these two quantities was then logarithmically rounded to the nearest decade, in microcuries, and entered in § 30.71, Schedule B. In the case of radionuclide krypton 85, the quantity was set at 100 microcuries to limit the external dose rate due to beta radiation. . . .
>
> It is considered highly unlikely (emphasis added) that under the provisions of the proposed exemption, any individual would inhale or ingest more than a very small fraction of any radioactive material being used or that any individual would receive excessive doses of external radiation.

Contact: Joseph C. Wang, NMSS
(301) 415-7909

In codifying § 30.14 (exempt concentrations) and § 30.18 (exempt quantities), the Commission was silent on possible exposures to members of the general public from using multiple exempt concentrations or exempt quantities. Also, the original technical base for § 30.14 and § 30.18 may need to be examined in light of the revision of the 10 CFR Part 20 concentration limits in air for members of the general public. Further, the Commission may not have anticipated that multiple exempt concentrations or quantities received by unlicensed facilities under these sections would be further processed by members of the general public (i.e. non-radiation workers) in these facilities. Although exposures to members of the general public in the range of 1 to 10 millirems may not be significant (see Attachments 1 and 2 below), the aggregate of several exposures may be significant when considering the number of practices the Commission has authorized and in re-examining the technical base for consumer products regulations.

Listed below are several examples where exposures to members of the general public from using either multiple exempt concentrations or quantities received pursuant to either § 30.14 or § 30.18 may occur:

- Attachment 1 is License No. 41-15597-01E, issued in 1973, to ERA Systems, Inc. (ERA), pursuant to section 32.18 of 10 CFR Part 32, authorizing the distribution of exempt quantities of C-14 to members of the public without further regulatory control. The C-14 chemical solution authorized for distribution under License No. 41-15597-01E is highly volatile and is used to evaluate the level of micro-organic-residue in solvents or directly on surfaces. The deposited contents are then permitted to evaporate. Based on the information submitted by the licensee, the staff believes it is possible that non-radiation workers performing the C-14 deposition/evaporation operation can receive annual inhalation exposures greater than 5 millirems per year.[1]

- Attachment 2 is a staff analysis on potential exposure to non-radiation workers in an unlicensed electronic facility processing neutron irradiated semiconductor silicon material (NDT-silicon) received pursuant to § 30.14. Although the staff's analysis shows that the dose to these non-radiation workers from lapping and cutting of the NDT under "wet" conditions is not

[1] The licensee's calculation was based on a typical laboratory with dimensions of 4 meters x 5 meters x 6 meters, with 20 room air exchanges per hour, and ten tests per hour with air releases of .055 microcurie of C-14 per test. The licensee also assumed that 90 percent of the C-14 released will go directly into the environment. The staff believes these assumptions are not sufficiently conservative. Using realistic but more conservative assumptions such as air releases of .22 microcurie of C-14 per hour, 4 room air exchanges per hour, and hood ventilation efficiency of 70 percent, the staff calculates the annual inhalation dose to a worker in the facility to be approximately 6.8 millirems per year.

significant, the analysis shows that if the lapping and cutting operations are performed "dry", the operations can generate contamination levels on the floor of the unlicensed facility which will exceed NRC's criteria for contamination control (i.e. Regulatory Guide 1.86) by a factor of almost 16.

- Attachment 3 is a NRC letter to Ronan Engineering Company (Ronan) acknowledging that the distribution of multiple exempt quantities is not prohibited by 10 CFR Part 32. Pursuant to § 32.19, Ronan is advising its unlicensed customers to purchase 10 exempt quantity sources from a specific licensee and to place them into a device, shipped separately from the sources, designed by Ronan. Further, 10 CFR Part 32 places no limit on how many such sources a distributor of exempt quantities can ship to an unlicensed customer.[2] Although Ronan provides its customers with safety instructions for putting together the device, there is no assurance that these instructions will be followed or that the devices will meet NRC's safety requirements since these devices are not subject to NRC regulation. However, Ronan's customers, pursuant to § 30.18(c), are prohibited from commercial redistribution of the materials.[3]

On August 17, 1994, Mr. Bernero sent to Mr. Beckjord a request for rulemaking proposing to add new sections 10 CFR 30.21 and 10 CFR 32.30-32.33 to 10 CFR Parts 30 and 32 (Attachment 4). Codification of § 30.21 and §§ 32.30-32.33 will authorize, for distribution, a number of devices containing small quantities of byproduct materials exempt from further NRC regulatory control which currently can only be received by a member of the public through a general or specific license. Since radioactive materials sealed in these devices pose little or no potential for causing a significant exposure to a member of the general public, to require users of these devices to hold either a specific or general license appears to be unduly burdensome not only to users, but also to distributors and regulatory agencies. In the case of Ronan, distribution of such devices, with the sources already incorporated, can be made directly to members of the general public, thereby eliminating the need for members of the general public to handle sources.

It is our understanding that the Office of Nuclear Regulatory Research (RES) already has a contractor study to re-examine the technical base for NRC's consumer products regulations in light of the new 10 CFR Part 20. We request that the contractor expedite its evaluation of exempt concentrations and

---

[2] In theory, a member of the general public can legally receive sealed and unsealed radioactive materials in total quantities that may exceed the lower limit of materials authorized under a general or specific license.

[3] The public exposures of concern are due to assembly or processing of multiple exempt concentrations or quantities. Exposures to members of the general public from devices containing these low-amounts of radioactive materials, after the initial assembly or processing of the materials, are generally insignificant.

quantities to examine whether some activities (e.g., non-radiation workers processing materials received under § 30.14 or § 30.18) should be restricted under revised Parts 30 and 32, and whether § 30.71 Schedules A and B should be revised in light of the new 10 CFR Part 20 dose requirements. Should rulemaking be necessary, it should be co-ordinated, if possible, with the high priority rulemaking activity to add new § 30.21 and §§ 32.30-32.33. The two major groups of users of calibration sources are either instrument (i.e., devices) users, which receive these sources as part of exempt devices, and general or specific licensees that need to use the calibration sources outside of a device. Since the principle use of exempt quantities is for calibration of instruments, we believe restricting activities currently allowed under § 30.18 would not have a major impact on users providing § 30.21 and §§ 32.30-32.33 are also codified.

Attachments:
1. License No. 41-15597-01E
2. Staff Evaluation of Application to Distribute NTD-Silicon
3. Ltr fm R. Baer to B. Cahill dtd 6/3/94
4. Memo fm R. Bernero to E. Beckjord dtd 8/17/94

DISTRIBUTION: Closes IMNS-869 CEstep
CPaperiello EWBrach IMAB R/F IMNS Central File MRothschild, OGC
NRC File Center PVacca SBaggett JLubinski CJones JBCarrico
SGreen NMSS r/f DCool(RES) CTrottier(RES) [redacted](RES) RFonner(OGC)
G:\IMNS869.JCW

OFC	IMAB	C	IMAB	C	IMAB		SCDB	C	DD/IMNS		D/IMNS	
NAME	JCWang		JMPiccone		MFederline		RBaer		EWBrach		CJPaperiello	
DATE	12/14/94		12/14/94		12/14/94		12/15/94		12/16/94		12/16/94	

C=COPY E=COVER/ENCLOSURE N=NO COPY OFFICIAL RECORD COPY

UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

BYPRODUCT MATERIAL LICENSE

E R A Systems, Inc.

License No. 41-15597-01E

Pursuant to the Atomic Energy Act of 1954, as amended; 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material"; Section 32.18, 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material"; and application dated April 6, 1973, as amended May 2, 1973, a license is hereby issued to E R A Systems, Inc., 4048 Brookfield Circle, Chattanooga, Tennessee 37412, to distribute Carbon 14 to persons exempt from licensing pursuant to Section 30.18, 10 CFR Part 30.

This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and other applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect.

This license shall expire on May 31, 1978.

FOR THE ATOMIC ENERGY COMMISSION

Original Signed By
Nathan Bassin

Materials Branch
Directorate of Licensing

Date May 25, 1973

/

Attachment 1

UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

BYPRODUCT MATERIAL LICENSE

E R A Systems, Inc.

License No. 41-15597-01E

Pursuant to the Atomic Energy Act of 1954, as amended; 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material"; Section 32.18, 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material"; and application dated April 6, 1973, as amended May 2, 1973, a license is hereby issued to E R A Systems, Inc., 4048 Brookfield Circle, Chattanooga, Tennessee 37412, to distribute Carbon 14 to persons exempt from licensing pursuant to Section 30.18, 10 CFR Part 30.

This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and other applicable rules, regulations, and orders of the Atomic Energy Commission now or hereafter in effect.

This license shall expire on May 31, 1978.

FOR THE ATOMIC ENERGY COMMISSION

Original Signed By
Nathan Bassin

Materials Branch
Directorate of Licensing

Date May 25, 1973

/

Attachment 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MATERIALS LICENSE

E R A SYSTEMS, INC.

License No. 41-15597-01E
Amendment No. 01

In accordance with letter dated April 12, 1977, License Number 41-15597-01E is amended in its entirety to read as follows:

Pursuant to the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1954, as amended, (Public Law 93-438); 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material;" Section 32.18, 10 CFR Part 32, "Specific Licenses to Manufacture, Distirubte, of Import Certain Items Containing Byproduct Material;" application dated April 6, 1973; letters dated May 2, 1973, and April 12, 1977, and enclosures thereto from the licensee; a license is hereby issued to E R A Systems, Inc., (4048 Brookfield Circle, Chattanooga,) Tennessee 37412, to distribute Carbon 14 to persons exempt from licensing pursuant to Section 30.18, 10 CFR Part 30.

This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and other applicable rules, regulations, and orders of the U. S. Nuclear Regulatory Commission now or hereafter in effect.

This license does not authorize possession of licensed material.

This license shall expire on May 31, 1978.

For the U. S. Nuclear Regulatory Commission

Original Signed By
NATHAN BASSIN

Radioisotopes Licensing Branch
Division of Fuel Cycle and Material Safety

Date JUN 7 1977

MB 6/6/77

1

E R A Systems, Inc The MESERAN Company
50 North Crest Road P O Box 3609 Chattanooga, TN 37404
TEL: (615) 266 0400 FAX: (615) 698 2633

May 14, 1994

MEMORANDUM

To: U S Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Industrial and Medical Nuclear Safety
Medical, Academic, and Commercial Use Safety Branch
Attn: Joseph C. Wang, Senior Health Physicist

From: John L. Anderson, President and RSO

Subj: License Renewal Application - No 41-15597-01E (C/N 021618)

On issuance, there should be only two authorized addresses from which shipments can be made:

1. 50 North Crest Road Chattanooga, TN 37404 and
2. 7909A Old Lee Highway Ooltewah, TN 37363.

Attached are the following documents to update and to replace all prior communications with respect to the subject license:

1. Typical label for 2 uCi sealed-in-glass ampule of MOR-SOLUTION *AK*. This particular solution contains tetrabromoethane-1,2-C14 in 0.6 ml of cyclopentane. Other similar labels may be designated MSS, SMC, TS, etc. in place of MOR. This label sheet is supplied to meet the requirements of 10 CFR 32.19 (c). Each label is secured with at least two pieces of transparent adhesive tape.

2. A brochure meeting the requirements of 10 CFR 32.19 (d) entitled 'MSS-SOLUTIONS (tm) - Shipping authority in the United States'. As in paragraph 1 above, the MSS designation may be replaced by the other character strings dependent on the particular market for the product.

3. A statement describing the normal and routine activities carried out under the subject license.

4. A typical MSDS and SURVEY OF USE APPENDIX.

5. A description of the quality control procedures that insure compliance with the requirements of 10 CFR 32.19 (a) and (b).

6. A sample invoice record of a shipment of C-14 containing material showing the quantity of byproduct material transferred as specified in 10 CFR 32.20 (a).

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

ERA SYSTEMS, INC CHATTANOOGA, TN 37404
RADIOACTIVE MATERIAL UN 2910
USNRC EXEMPT 2 uCi C14/AMPULE
AK CODE 940405

E R A Systems, Inc.
(615) 266 0400

50 North Crest Road
Chattanooga, TN 37404-1828

MSS-SOLUTIONS (tm) - Shipping Authority in the United States

MSS-SOLUTIONS are shipped by E R A Systems, Inc. in interstate commerce under the authority of U. S. Nuclear Regulatory Commission License No. 41-15597-01E which authorizes such shipments under Sections 32.18 and 32.19 of 10 CFR Part 32. This license permits the distribution of carbon-14 to persons EXEMPT from licensing pursuant to Section 30.18, 10 CFR Part 30. Shipments are made in accord with applicable DOT regulations for radioactive materials, limited quantity, n.o.s., UN 2910. (Cf. 49 CFR 173.421). No external radioactive labels are required. The enclosed materials are EXEMPT from USNRC or Agreement State licensing requirements. These MSS-SOLUTIONS contain FLAMMABLE components.

MSS-SOLUTIONS contain C-14 Radioactive Material--Not for Human Use--Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commerical Distribution is Prohibited--Exempt Quantities Should Not be Combined.

Special Instructions

HANDLING: MSS-SOLUTION ampules should be handled with care to prevent accidental breakage and release of components. In case of accidental breakage or spillage, all affected ares of the body should be washed promptly with soap and water. The adjacent area should be temporarily evacuated to reduce to a minimum inadvertent inhalation of vapors..

USE: These materials are sold and distributed for use only with the CON-TROL-CURE (R) INK-CURE (tm) ANALYZER and in accordance with the instructions listed in the Technical and Operating Manual of the CON-TROL-CURE INK-CURE ANALYZER. See also MSDS and attached Survey of Use for calculated exposure conditions.

STORAGE: Prior to use the MSS-SOLUTION ampules should be stored whereever convenient but preferably in an area which limits access only to authorized persons. Opening, transferring to a vial, and capping should be carried out within the ANALYZER enclosure with continuous venting to the outside environment or within an exhaust hood.

DISPOSAL: MSS-SOLUTIONS may be discarded in liquid form by permitting evaporation within an exhausting area. All MSS-SOLUTION components are volatile.

Approved: May 1, 1993

John L. Anderson

E R A Systems, Inc The MESERAN Company
50 North Crest Road P O Box 3609 Chattanooga, TN 37404
TEL: (615) 266 0400 FAX: (615) 698 2633

STATEMENT OF ACTIVITIES CARRIED OUT UNDER USNRC LIC. # 41-15597-01E

E R A Systems, Inc. supplies carbon-14 labeled byproduct material to purchasers of analytical instruments manufactured and supplied by the Company for the purposes of (1) quantifying the level of crosslink density in polymers and (2) determining the levels of micro-organic residues on surfaces and as non-volatile residues (NVR) in liquids by testing deposited residues. Only very occasionally, the technology of Evaporative Rate Analysis is applied to other types of measurements such as the characterization of surfaces by ab- and/or ad-sorptive processes.

The radioactive C-14 materials are purchased in bulk from other suppliers and are diluted and assayed in preparing the requisite extremely dilute solutions of high-boiling but-volatile carbon-14 labeled compounds in low boiling non-radioactive solvents (at least 1:50,000). The possession, use, formulation, and storage of byproduct material is carried out under a State of Tennessee Radioactive Materials license. The precisely formulated solutions are shipped under USNRC License No. 41-15597-01E as sealed-in-glass ampules to protect solution integrity and to prevent inadvertent evaporation of low boiling solvent and high boiling radiochemical prior to use as well as to preclude inadvertent contamination during shipment and storage. Each user rarely exceeds depositing the radioactive solutions onto a test surface in quantities greater than 0.15 uCi C14 and routinely in quantities of no more than 0.08 uCi C14 per test.

There are four standard ampule sizes: (1) 0.215 ml containing 1.1 uCi C14/ampule; (2) 0.6 ml containing 2 to 4 uCi C14/ampule; (3) 0.8 ml containing 12.9 uCi C14/ampule; and (4) 1.6 ml containing from 4.0 to 10.4 uCi C14/ampule. Of these (1) is being discontinued in 19 months, (2) is the new standard size for solvents classed as poisons in interstate shipments, (3) has only one customer, and (4) is the now designated 'XL' size.

Very rarely, customers request shipments of these solutions in individual ampules up to 80 uCi C14.

Please refer to the Material Safety Data Sheet and the Survey of Use Appendix for detailed information on properties and exposure limits under normal conditions of use.

E R A Systems, Inc. The MESERAN Company

MESERAN MOR-SOLUTION *AK* MARCH 1, 1994

MATERIAL SAFETY DATA SHEET

(Based on OSHA 174 September 1985 with 03/01/89 exposure limits and 10 CFR Part 20 (U S Nuclear Regulatory Commission) published in the Federal Register May 21, 1991)

PRELIMINARY STATEMENT

This document describes the health hazards of MESERAN MOR-SOLUTION *AK* by describing its two components: Tetrabromoethane-C14 and Cyclopentane. They are present in an approximate ratio of 1:100,000; both must individually and collectively be considered health hazards although, as is seen in the MSDS APPENDIX survey below, the exposure levels even under adverse circumstances are extremely low. This survey shows the actual exposure limits encountered in normal use during MESERAN Micro-Organic-Residue Analyzer operation as well as those associated with accidental breakage of ten ampules at one particular instant within the laboratory.

Specifically the document includes pertinent data on tetrabromoethane-C14 and cyclopentane as individual components The letters (in parentheses) that precede the names are those used in the MESERAN MOR-SOLUTION *AK* designation. The *AK* formulation is designed specifically for quantifying most micro organic residues. The factory preformulated MESERAN MOR-SOLUTION *AK* is named as follows: *A* designates the Radiochemical; *K* designates the Solvent. Each ampule of *AK* contains 15.8 ug (5.2 uCi) of tetrabromoethane-C14 in 1.6 ml of cyclopentane.

SECTION I

Manufacturer's Name and address

E R A Systems, Inc.
The MESERAN Company
50 North Crest Road
P. O. Box 3609
Chattanooga, TN 37404-0609

Emergency Telephone No. (615) 875 3931
Information Telephone No: (615) 266 0400
Date Modified March 1, 1994

SECTION II Hazardous Ingredients/Identity Information

Radiochemical: Listing not required by OSHA due to conc. (< 0.01%); included for its radioactivity.

A) 1,1,2,2-Tetrabromoethane-C14 CAS # 79-27-6
a.k.a Acetylene tetrabromide Molecular formula C2H2Br2

Solvent:

(K) Cyclopentane CAS # 287-92-3
a.k.a. Pentamethylene Molecular formula C5H10

SECTION III Physical/Chemical Characteristics of Components

Radiochemical:

(A) 1,1,2,2-Tetrabromoethane-C14 bp: 243 C with decomp; 151C/54mm
Colorless to yellow liquid, pungent odor d: 2.9638 @ 20/4
Slightly sol water, sol most organics mp: -1 C

Solvent:

(K) Cyclopentane bp: 48 C mp: -94 C
Flammable; colorless, volatile liquid, mild odor fl p: 19 F
Low solubility water; soluble most organics d: 0.75

SECTION IV Fire and Explosion Hazard Data (Components)

Radiochemical: Due to the extremely small quantity in each ampule, there is no hazard in this category.

Solvent: Solvent (*K*) cyclopentane is HIGHLY FLAMMABLE with a flash point below room temperature. Thus it must be considered dangerous even in the very small quantities involved. Fires should be extinguished by carbon dioxide or dry chemical powder. No water. No special personnel gear required. Unusual fire and explosion hazards: This flammable solvent forms explosive mixtures in air--but the extremely low quantities involved almost preclude any realistic hazard unless a large number of the ampules are broken at one time (a most unlikely circumstance due to the method of packaging).

SURVEY OF USE

DESCRIPTION

This amount of C-14 labeled material is classified under the EXEMPT status in U. S. Nuclear Regulatory Commission and/or "Agreement State" rules and regulations: In general, up to 100 microCuries of C-14 within a single ampule may be possessed and used without a specific license and multiple ampules without limit may be stored in inventory. Certain other restrictions may also apply; for example, if a Company has a specific license from an "Agreement State" for another application, the possession and use of otherwise EXEMPT quantities *MAY* be required under that license or an extension thereof. Under its USNRC license to distribute EXEMPT quantities of C14 labeled material, E R A Systems, Inc. cannot ship at any one time to a single destination more than a total of 1 mCi of MESERAN MOR-SOLUTION ampules in the aggregate of which no single ampule may contain more than 100 microCuries. (Cf. 10 CFR 32.19)

NOTE: WHEN OPERATING UNDER THE "LICENSE EXEMPT" RULES, UNDER NO CONDITIONS MAY THE TOTAL AMOUNT OF RADIOCHEMICAL IN ANY SINGLE QUANTITY OF ANY MIXTURE EXCEED THE MAXIMAL ALLOWABLE USNRC AND/OR "AGREEMENT STATE" LIMIT OF 100 MICROCURIES OF C-14.

Ampules of MESERAN MOR-SOLUTION *AK* are designed for use in MESERAN Micro-Organic-Residue Analyzers only. The ampule and its contents of completely volatile chemical constituents are neither knowingly sold nor distributed nor are they authorized for any other purpose by E R A Systems, Inc., The MESERAN Company. The specific uses of these and other formulations are detailed in the MESERAN Technical and Operating Manual supplied with each MESERAN Micro-Organic-Residue Analyzer and/or in Application Bulletins or their equivalent supplied at various times by E R A Systems, Inc., The MESERAN Company.

The contents of each ampule (1.6 milliliters) are user transferred by gravity into a 2 milliliter glass vial from which it is removed by means of a microsyringe in 17 ul quantities. Such a transfer is routinely made with virtually no loss or spillage although use of rubber gloves or finger cots for the transfer within a hooded environment is recommended. See applicable OSHA guidelines and regulations, if any.

Used to evaluate the level of micro-organic-residue in solvents or directly on surfaces, approximately 1/90 of the ampule contents (nominally 17 ul) are routinely deposited in each test sequence onto a watchglass or other surface. The deposited contents are then permitted to evaporate within a plastic enclosure while evaporative data are recorded. Following data acquisition, the vaporized contents are exhausted to the rear of the system and should properly be directed to a hood or other exhaust mechanism. Under these conditions considerably less than 10% of the vaporized contents escape to the laboratory environment.

Radiochemical Limit

AMOUNT OF RADIOCHEMICAL RELEASED PER 17 UL DEPOSITION

	ml (gas)	uCi C14
Tetrabromoethane-C14 (A)	**0.000013**	**.055**

Assuming a laboratory of 4 meters x 5 meters x 6 meters dimensions and 20 air changes per hour, ten tests per hour (considered the maximum number of tests possible including analysis and time for sample insertion) released and exhausted to the outside air with an minimal efficiency of 90% provides no more than the following airborne concentrations within the laboratory environment:

	OSHA Standards			USNRC limits for
	Actual Air (ppm)	8 hr workplace (ppm)	Actual uCi/ml/hr	release to unrestricted areas uCi/ml
Tetrabromoethane-C14	6 E - 9	1	3 E - 11	3 E - 9 *

E R A Systems, Inc The MESERAN Company
50 North Crest Road P O Box 3609 Chattanooga, TN 37404
TEL: (615) 266 0400 FAX: (615) 698 2633

Quality Control Procedures to Assure Compliance with 10 CFR 32.19 (a) and (b)

Assays:

All assays of C-14 labeled solutions are carried out using a Packard Liquid Scintillation Spectrometer based on reference C14 standards.

These assays are carried out on master batch formulations of C-14 labeled compounds in cyclopentane as well as on final very dilute formulations prior to packaging in Pyrex sealed-in-glass ampules which have been scrupulously cleaned prior to filling.

After packaging random samples of ampules are deliberately opened for reassay to assure proper packaging assays.

All ampules are promptly and properly labeled shortly after sealing.

All assays and packaging operations are carried out by responsible and qualified professionals

Shipping:

No outer package is ever offered for shipment with more than 800 microCuries of C-14 in sealed-in-glass ampules of less than 80 microCuries per package.

All packaging for shipment is personally inspected and approved by at least one qualified professional to insure compliance with the provisions of 10 CFR 32.19(a)&(b).

E R A Systems, Inc
The MESERAN Company
50 North Crest Road
P O Box 3609
Chattanooga, TN 37404-0609

TEL: (615) 266 0400
FAX: (615) 892 2633

May 14, 1994

INVOICE **No. SAMPLE**

Billing Address
XXXXX
XXXXX
XXXXX

Shipping Address
YYYYY
YYYYY
YYYYY

Terms: Net **PO:** 64753 **Customer PO:** T915290

Item	Description	Qty	Unit Price	Total
1	MSSRED 10 AMPULE PKG (UVPS-M002-007)	2	180.00	360.00
2	UPS			6.00
			Total Price	**$366.00**

This shipment contains 20 C14 ampules with a total of 22 microCuries C14.

Docket No.: 03033072
Mail Control No.: 021283

STAFF EVALUATION OF MISSOURI UNIVERSITY RESEARCH REACTOR'S (MURR) APPLICATION FOR AN EXEMPT LICENSE TO DISTRIBUTE NEUTRON TRANSMUTATION DOPED SEMI-CONDUCTOR MATERIALS

The irradiated semiconductor material (i.e., NTD-Silicon) released under the E-distribution license will be processed by workers, not subject to NRC or Agreement State regulatory control, for incorporation ultimately into various electronic components. This processing is expected to include cutting and lapping of the semiconductor materials by these workers. Lapping is a double-sided abrasive process designed to remove a thin layer from each side of a semiconductor wafer. A survey performed by MURR found that this process is usually carried out in the presence of ambient water which is required to prevent localized temperature increases that could result in undesirable annealing in the material. The water and the fines resulting from cutting and lapping procedures is generally sent to the sanitary sewer system or the waste water is collected in a settling tank where the fines are removed and disposed of in a landfill and the water pumped to the sanitary sewer. Once the NTD-Silicon is incorporated into the electronic components, the annual dose to the public from the electronic components is expected to be negligiable for reasons stated below. Therefore, this evaluation will not address the individual or collective doses due to the final electronic components. The evaluation will address the following:

- The total effective dose-equivalent (TEDE) to workers from process and assembly of the NTD-Silicon into the final electronic components. The TEDE will be the sum of the external and the internal radiation exposure.

Attachment 2

- The annual radiation exposure to the public, other than workers processing and assembling the NTD-Silicon. This exposure will be due mainly to the disposal of NTD-Silicon fines generated from cutting and lapping operations.

- Exposure to the public resulting from an accident at an unlicensed facility processing and assembling the NTD-Silicon

A. Annual Radiation Exposure to Unlicensed Workers From Assembly of the NTD-Silicon

The group among the public that is the most likely candidate to receive the highest exposure from the NTD-Silicon are the workers, not subject to NRC or Agreement State regulatory control, performing the cutting, lapping, and assembly of NTD-Silicon into the electronic components. The total exposure will be the sum of external dose due to direct radiation and internal dose from the inhalation and ingestion of the NTD-Silicon.

(1) Direct Radiation Exposure

The direct radiation exposure will be due to exposures from (a) the processing and assembly of the NTD-Silicon and (b) the handling of the NTD-Silicon fines collected from the waste settling tank.

(a) Direct Radiation Exposure From Process and Assembly

MURR's application stated that workers, not subject to NRC or Agreement State regulatory control, typically will be handling NTD-Silicon cylinders that are 3 inches in diameter by 10 inches long. MURR calculated the surface dose rate of this bar (for Co-60) to be 0.03 mR/hr, assuming no self-shielding. Since MURR's expected annual production limit for distributing NTD-Silicon will be 50 metric-tons, it is reasonable to assume that NTD-Silicon will be processed in an assembly line fashion and that a worker can be exposed to radiation from the NTD-Silicon at the rate of 2,000 hours per year (i.e., 40 hours per week, 50 weeks per year). Based on MURR's calculation and assuming the worker is in direct contact with the NTD-Silicon, this could result in the worker receiving approximately 60 millirems per year.

Per staff's request, MURR submitted additional information on March 8, 1993. Table R2 gives the upper impurity concentrations in the NTD-Silicon based on a 27 hour irradiation at a thermal neutron flux density of 1 x 10E13 n/cm**2/sec and a decay period of approximatley 56 hours. For Co-60, the maximum expected percent of exempt concentration (MEC) is .04%. The staff verified that the sum of all ratios of each radionuclide (i.e., sum of the maximum expected percent of exempt concentration divided by 100%) has not exceeded 1. The highest MEC among the short-lived radionuclides (less than 180 days) is due to Ca-45 (33%) which has a half-life of 165 days and is a pure beta emitter with a maximum beta energy of 250 KeV. Among the long-lived radionuclides in

MURR's table R2 (greater than 180 days), Eu-152 (6.7%) is by far the greatest contributor. The staff therefore calculated the direct radiation exposure to a worker due to a 3 inch diameter by 10 inch NTD-Silicon cylinder containing 10% Eu-152 at 1 foot away from the worker, using the computer code MicroShield 4.0, to be 3.18E-4 mrem/hr or .636 mrems/year.

In addition to the gamma whole body exposure, the contribution from the beta dose due to P-32 has been analyzed by the applicant. MURR estimated that the annual external dose to the skin, using the computer code VARSKIN, is less than 1 mrem.

(b) Direct Radiation Exposure From Collection of NTD-Silicon Fines

The direct radiation exposure from collection of NTD-Silicon fines would be due mainly to Eu-152. For conservatism, the staff assumes that one U.S. company receives all MURR's annually generated 50 metric-tons of NTD-Silicon and that 1% of the NTD-Silicon result in fines to be collected at the settling tank. This amounts to approximately .032 mCi of Eu-152 in the fines at the time of annual collection, resulting in a point source dose-rate of .2 mr/hr at 1 foot. Workers spending a half-hour packaging the fines should not receive more than 0.2 mrem whole body exposure. If the same workers are used to perform both processing of NTD-Silicon and disposal of the NTD-Silicon fines, the total annual direct exposure from these operations should be less than 1 mrem.

(2) Internal Radiation Exposure From Process and Assembly

MURR (the applicant) states that the American Conference of Government Industrial Hygienists (ACGIH) recommends a silicon dust concentration limit in the workplace of 10 milligrams/m**3. Based on the ACGIH standard, the applicant argues if the silica dust limit is exceeded, then the health of workers will be affected more from silica dust than from the radiation in the dust.

Table R1 on page 3 of the applicant's March 8, 1993, response gives the work area CEDE (Committed Effective Dose-Equivalent in mrem/year), not TEDE as stated by the applicant, for radionuclides in the NTD-Silicon with half-lives greater than 120 days. The staff independently calculated the submitted CEDE by MURR for Co-60 (2.5 mrems/year) and Eu-152 (3.5 mrems/year) and found them to be in agreement with those of the applicant.

It is important to note that the staff has asked MURR to calculate the dose to workers from lapping and cutting of NDT-Silicon under "dry" conditions and not "wet". In addition, the staff has also asked MURR to calculate the dose to workers for each long-lived radionuclide with the concentration of each radionuclide up to the concentration limit under Schedule A of 10 CFR 30.70. Based on Table R2 of the applicant's March 8, 1993 response, the dominant long-lived radionuclide that will contribute to internal dose is Eu-152 (7% of total). Co-60's contribution to the dose, comprising .04% of the total activity in the NTD-Silicon, will not be significant. Assuming 10% of the total

activity in the NTD-Silicon (contributions from all other radionuclides should be less than 3% of Eu-152) will be Eu-152, the CEDE from "dry" cutting and lapping operations will be 0.35 mrem/year from inhalation.

The staff agrees with the applicant that the internal hazard due to ingestion will be affected more by the chemical toxicity of the silica dust than its radioactivity. For conservatism, the staff assumes that 50 metric-tons of the NTD-Silicon is processed at one U.S. facility and that 1% of the incoming silicon ingots are generated as fines. As an example, in order for an unlicensed worker to receive 1 mrem/year from ingestion, that worker would have to ingest 2,268 grams of silicon fines over the year, an unlikely situation. The staff therefore makes a more realistic asumption that approximately 23 grams of silicon is ingested per year resulting in an annual internal dose of 0.01 mrem, due to ingestion.

(3) Total Effective Dose-Equivalent From Processing and Assembly

The total effective dose-equivalent (TEDE) from processing and assembly of the NTD-Silicon is the sum of the external and internal dose received by the non-licensed workers. They are:

TEDE (dry) = .64 (external) + .36 (internal) = 1.00 mrem/year

TEDE (wet) = .64 + .2 (external) + .01 (internal) = 0.84 mrem/year

Since the NTD-Silicon is currently being processed wet, the 0.84 mrem/year is the more realistic dose estimate. Also, due to the limited number of workers in this area, the staff believes the collective dose to the public should not be significant.

B. Annual Radiation Exposure to Members of the General Public Not Associated With Assembly of the NTD-Silicon

Once the NTD-Silicon has been cut and incorporated into various electronic components, based on the dose estimates to the NTD-Silicon workers, the dose to a maximally exposed member of the general public from the electronic components is expected not to be significant. This is because direct radiation from the NTD-Silicon will be (1) attenuated by the electronic component(s) surrounding the chip, (2) the size of the NTD-Silicon chip will be much smaller than the initial ingot that originally came into the factory, and (3) other than workers assembling the NTD-Silicon, other members of the general public will not be as close nor spend nearly as much time in the vicinity of the NTD-chips. However, the dose to the public from NTD-Silicon fines generated from cutting and lapping needs to be further evaluated.

(1) Disposal of NTD-Silicon Fines From Wet Processing and Assembly

As described earlier, water and fines resulting from cutting and lapping procedures is generally sent to the sanitary sewer system or the waste water is collected in a settling tank where the fines are removed

and disposed of in a land fill. For conservatism, the staff assumes that 50 metric-tons of NDT-Silicon is processed annually at one unlicensed facility and that 1% of the NDT-Silicon (i.e., 0.5 metric-ton) is generated as fines for release into the sanitary sewer or a landfill. Since Eu-152 is by far the most abundant long-lived radionuclide found in MURR's NDT-Silicon, the staff assumes 10% of the total activity in the NDT-Silicon is due to Eu-152. This results in a total activity of 32 microcuries of Eu-152 fines generated annually. The dose to a maximally exposed individual member of the public from this amount of annual release to the sanitary sewer can be derived from NUREG/CR-5814 titled, "Evaluation of Exposure Pathways to Man From Disposal of Radioactive Materials Into Sanitary Sewer Systems", prepared by Pacific Northwest Laboratory (PNL). In this study, PNL found that the external dose to a maximally exposed individual member of the general public can be 10 mrems/year for an annual release of Co-60 approaching 1 curie. This translates to a dose of 1.7E-4 mrem/year for an annual release of 32 microcuries of Eu-152. Since NUREG/CR-5814 evaluated the dose to a maximally exposed individual member of the general public which can be a sewer sludge operator or a landfill equipment operator (assuming the sludge goes to the landfill), the staff concludes that public exposure from disposal of the fines to either a sanitary sewer or to a landfill is not significant.

(2) Disposal and Contamination Control of NTD-Silicon From Dry Processing and Assembly

If the NTD-Silicon is processed dry, members of the general public, not associated with processing and assembly of the NTD-Silicon, will be exposed to the neutron-induced radioactive materials in the NTD-Silicon from two separate pathways. The first pathway is similar to the disposal of the wet NTD-Silicon fines described above. Since no additional fines will be generated through the dry process, the dose consequence to the general public for disposal of the fines will be no different from that for the wet process. However, there is a much higher probability for the NTD-Silicon dust to get out of the workplace into the environment for the dry process since the NTD-Silicon is no longer under NRC's or an Agreement State's regulatory control.

NRC's Regulatory Guide 1.86 states that for beta/gamma emitters, such as Eu-152, removable contamination cannot exceed 1,000 dpm (disintegration per minute) per 100 cm**2 for equipment leaving a licensee's radiological control area. With a concentration of 7.0 E-5 microcuries/gram of Eu-152 in the NTD-Silicon, this translates to 6.4 grams of silicon dust per 100 cm**2 on the workplace floor. Using the applicant's 10 mgm/m**3 chemical toxicity limit, assuming the air in the workplace is controlled to this level, and based on a resuspension factor of 10E-6, the silicon contamination on the floor of the workplace corresponds to 100 grams of silicon per 100 cm**2 or 15,625 dpm of Eu-152 per 100 cm**2. Thus, if we assume that the non-

licensed facility will control silica dust based on its chemical toxicity limit, NRC's criteria for contamination control (i.e., Regulatory Guide 1.86) will be exceeded by a factor of almost 16.

C. Accident Analysis

Assuming that all 50 metric-tons of NTD-Silicon is processed at one U.S. facility, the most likely accidental release of the radioactive materials to the public is that of a fire. Assuming a Chi/Q value of 1.0 E-3, the maximum dose (from Eu-152) to a individual member of the general public due to a fire is 0.13 millirem at 400 meters away.

JUN 0 3 1994

Ronan Engineering Company
Measurements Division
ATTN: Bon Cahill
General Manager
8050 Production Drive
Florence, KY 41042

Dear Mr. Cahill:

This letter is in response to your facsimile dated May 7, 1994, in which you asked for verification that the advice you plan to give to your customer will not put you, your customer, or the persons supplying sources under an NRC license issued pursuant to 10 CFR 32.18 in violation of NRC regulations.

Specifically, you plan to advise your customer to purchase 10 sources each having a quantity of byproduct material which does not exceed the applicable quantity set forth in 10 CFR 30.71, Schedule B, from a person specifically licensed by NRC pursuant to 10 CFR 32.18 and place them into a protective stainless steel tube, designed by Ronan. The customer is then advised to insert the tube into a mold housing opposite a radiation detector. You are advising your customer that he is exempt, pursuant to 10 CFR 30.18, from the requirements for a license to use the sources in this configuration.

The situation described in your facsimile does not violate any NRC regulations as long as your customer is not specifically licensed by NRC or an Agreement State and your customer receives the sources directly from the person licensed pursuant to 10 CFR 32.18.

If you have any additional questions, please contact me at (301) 415-8125 or Mr. John Lubinski of my staff at (301) 415-7868.

Sincerely,

Original Signed by

Robert L. Baer, Branch Chief
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety

cc: Vicki Jeffs
Radiation Control Branch
Cabinet of Human Resources

DISTRIBUTION:

SSSS Staff	SSSS r/f	SCDB r/f	NMSS r/f
IMNS c/f	JGlenn	JPiccone	PVacca
SGreene			

OFC:	SCDB JWL		SCDB MBB		OGC [illegible]		SCDB	
NAME:	JLubinski		SBaggett		RFonner for RW		RBaer RLB	
DATE:	06/03/94		06/03/94		06/3/94		06/3/94	

G:\RONAN.JWL

Affadvit 3

RONAN
Measurements Division

RONAN ENGINEERING COMPANY
MEASUREMENTS DIVISION
8050 Production Dr. Florence Ky. 41042 USA
(606) 342-8500 FAX (606) 342-6426

FAX

Date: 05/17/94
From: Bon Cahill
Number of Pages: 9

To: NRC
Attention: John Lubinski
Fax Number: 301-415-5369

Mr. Lubinski:

The application where the exempt sources could be applied is shown conceptually in the attached figure, D-9523-K.

By using a highly sensitive detector, we can do this application with CS-137 or CO-60 exempt sources in a source tube (rod) (see B-9392-K) and inserting the rod into a source well.

We would advise the customer to purchase exempt sources and place into a protective stainless steel tube B-9392-K and insert into a well inside the mold housing. The sources can be removed as required and the labeling on the sources is protected by the source tube or rod.

The customer would buy the detector, source rod, well and electronics from us. We would not only provide instructions on how to load the sources, but also provide safety instructions for handling, storage, and use, in addition to those supplied by the source supplier. (additional safety information, we would provide, is enclosed with this fax).

We believe that this procedure is in compliance with all the pertinent NRC regulations and need your verfication.

If you have any questions or need further information, please let me know.

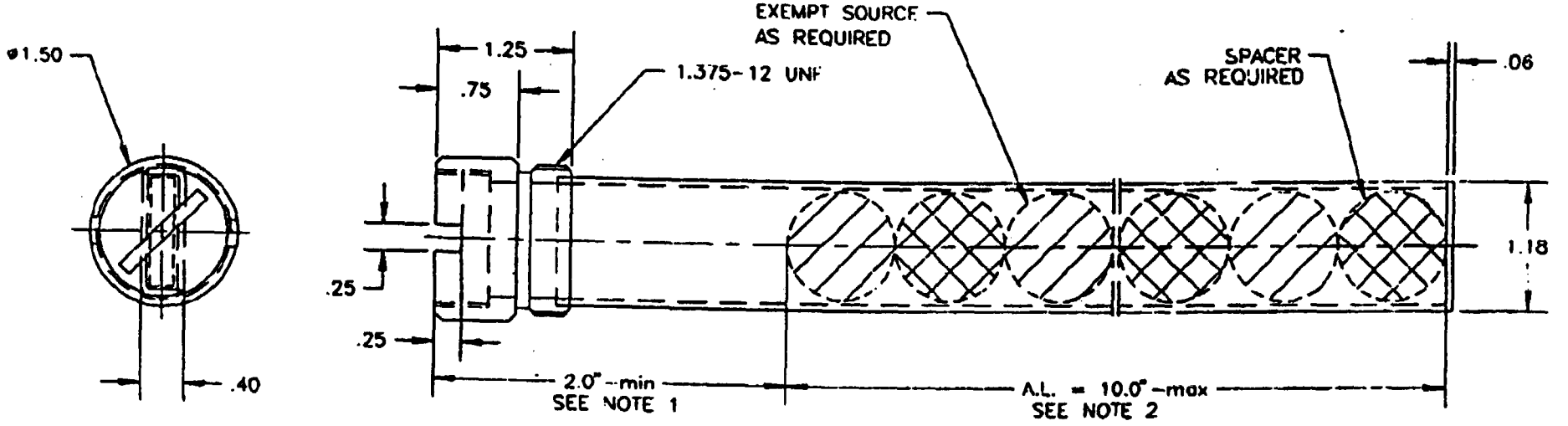
Thanks for your assistance,

Bon Cahill

Bon Cahill
General Manager
Senior Physicist

OK

DATE	SYM	REVISION RECORD	DR	CK
5/17/94	1	ADDED INFORMATION PER RC	YSP	



NOTES:

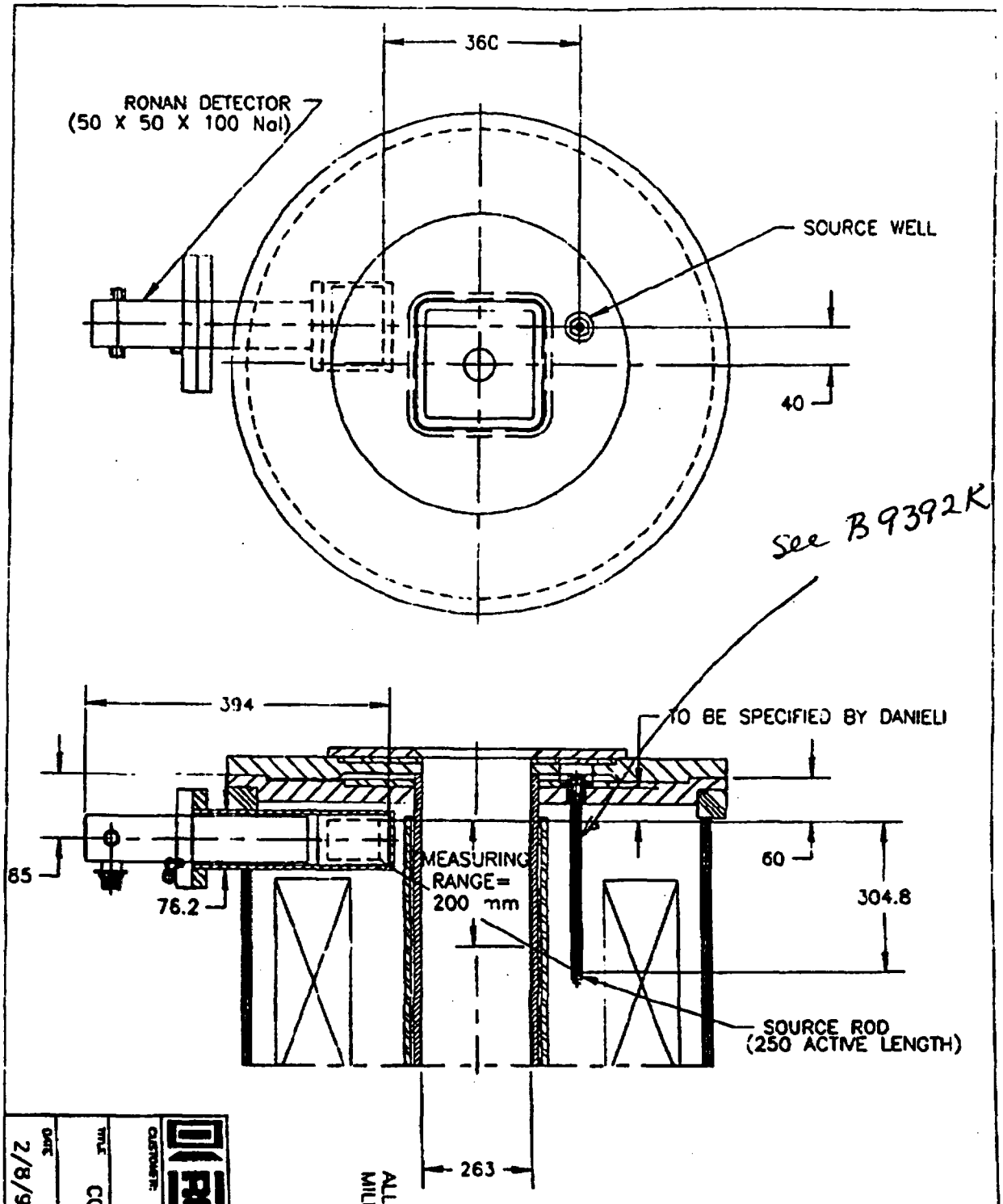
1. THIS DISTANCE IS TO BE SPECIFIED BY CUSTOMER.
2. A.L. – ACTIVE LENGTH. MAXIMUM NUMBER OF EXEMPT SOURCES ARE TEN.

RONAN MEASUREMENTS DIVISION

CUSTOMER:	SCALE: NTS	DR. BY YSP
		APPR. BY

TITLE: OUTLINE: EXEMPT SOURCE ROD

DATE	DRAWING NUMBER	REV
1/11/94	B-9392-K	1



ALL DIMENSIONS ARE IN MILLIMETERS.

RONAN MEASUREMENTS DIVISIO

CUSTOMER:

TITLE: CONFIGURATION: MOLD LEVEL GAGE

SCALE: NTS

DR. BY: YSP

APPR. BY:

DRAWING NUMBER: B-9523-K

REV:

DATE: 2/8/94

REVISION RECORD				DATE

INFORMATION REGARDING RADIOACTIVE SOURCES OF EXEMPT QUANTITIES OF BY PRODUCT MATERIAL

General: The federal regulations pertaining to the licensing for ownership, and use of byproduct radioactive material is found in CFR.10 part 30.

In paragraph 30.19, titled **"Exempt Quantities"**, it states that any person is exempt from the requirements for license if they possess the byproduct in individual quantities that does not exceed the applicable quantity set forth in paragraph 30.71 Schedule B.

For Cs-137, that quantity is 10 microCuries(μCi) and for C0-60, that quantity is 1 microCurie(μCi). For gaging these are the primary high energy isotopes used.

For simplicity, a user may receive possess and use an exempt quantity source without a license because it qualifies as **"Unlicensed Material"**.

The manufacturers of the exempt quantity source must possess a specific license and meet the requirements for the license under paragraph 32.18.

Under the condition of the license, the manufacturer must supply the exempt source quantity to the user individually packaged and no more than 10 such packaged quantities in a single transaction. The immediate container of each quantity shall bear a durable legible label which identifies the isotope and quantity of radioactivity and the words **Radioactive Material.**

In addition an accompanying brochure or label on the container states that the product is **Radioactive Material/Not for Human Use - Introduction into Foods, Beverages, Cosmetics. Drugs or Medicinals for Introduction into Products**

Manufactured for Commercial Distribution is Prohibited. Exempt quantities should not be combined. Also the accompanying brochure should contain radiation safety instructions pertaining to the safe handling, use, storage and disposal.

User Responsibilities:

A) Proper Storage: When not used, the exempt sources should be stored in a shielded container to prevent accidental damage to the sources and keep the radiation exposure as low as possible.

B) Proper Handling: The sources must be kept intact. The are not to be combined with each other or altered in any way so as to lose their identity as an individual exempt quantity. The label should be kept intact on the source and the sources preferably stored in separate individual containers. If multiple exempt sources are stored, they should be placed into a shielded container to keep the levels under 0.5mR/h on the surface.

C) Proper Use: The sources are intended to be used to provide ionizing radiation for gaging the level of steel.

The sources may also be used to test radiation detection instruments including survey meters.

The sources are not to be modified or broken apart. Nor may they be combined with each other to alter the exempt source content of the package.

When using several of the sources to provide ionizing radiation to a distributed or elongated detector, the sources should be kept sufficiently separated or shielded to

reduce the exposure to personnel.

D) Unshielded Radiation Exposure from Exempt Sources: Each exempt quantity source will provide a max radiation of 1mR/h on the surface (2") or 0.03mR/h at 1 foot away. At one meter or 39" the radiation is 0.003mR/h.

Normal background levels are 0.015 mR/h to 0.030mR/h so that the radiation from an exempt source is very difficult to detect, unless you get less than one foot from the source.

E) Recommended Shielding: Ronan recommends that based on personnel receiving a radiation exposure of no more than 100mR in a year, which is comparable to background exposure, that the sources be stored in a shield which limits the field to less than 0.5mR/h on the surface.

F) Disposal: A single exempt quantity may be disposed of safely through normal refuse disposal methods but is not meant to be incinerated. Exempt quantities should not be accumulated and lumped together for disposal.

"IMPORTANT"

INSTRUCTIONS FOR POSSESSION AND USE OF EXEMPT RADIOACTIVE MATERIAL

Certain quantities (30.71 B) of Radioactive Material are exempt from NRC or Agreement State licensing requirements.

Exempt radioactive material is not for Human use...introduction into foods, beverages, cosmetics, drugs or medicinals, or into products manufactured for commercial distribution...These quantities should not be combined.

HANDLING.

Disc Sources should be held by the metal or plastic sides or back. Be careful not to damage any foil used to cover the radioactive material.

Solid rod sources should be held at the end opposite the activity.

Never place radioactive material in the mouth, nor any items in contact with radioactive material in the mouth without first washing well to insure that the are free of contamination.

CONTAMINATION

Loose radioactive material may be cleaned up with small quantities of detergent in water and absorbent materials.

STORAGE

Store all sources in a secured container with visible identification. Always protect exempt sources when not in use.

INSTRUCTIONS FOR DISPOSAL OF EXEMPT RADIOACTIVE MATERIAL

INCINERATION

Never dispose of any exempt radioactive material or waste by incineration.

NORMAL REFUSE

Exempt radioactive material should be placed in a plastic or metal container, marked as waste, and placed in normal refuse.

These instructions apply only to the exempt material approved by the NRC [redacted] and are meant as guides for your safe handling of the sources. Radioactive material possessed under a specific license from the NRC or Agreement state must be handled in accordance with those specific license requirements.

§ 30.71 Schedule B.

Byproduct material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	1,000
Chromium 51 (Cr 51)	10
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	1
Cobalt 60 (Co 60)	100
Copper 64 (Cu 64)	10
Dysprosium 165 (Dy 165)	100
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	1
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	10
Europium 155 (Eu 155)	1,000
Fluorine 18 (F 18)	10
Gadolinium 153 (Gd 153)	100
Gadolinium 159 (Gd 159)	10
Gallium 72 (Ga 72)	100
Germanium 71 (Ge 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	10
Hafnium 181 (Hf 181)	100
Hafnium 182 (Hf 182)	1,000
Hydrogen 3 (H 3)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	100
Indium 115m (In 115m)	10
Indium 115 (In 115)	1
Iodine 125 (I 125)	1
Iodine 126 (I 126)	0.1
Iodine 128 (I 128)	1
Iodine 131 (I 131)	10
Iodine 132 (I 132)	1
Iodine 133 (I 133)	10
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	100
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	10
Iron 59 (Fe 59)	100
Krypton 85 (Kr 85)	10
Krypton 87 (Kr 87)	100

Byproduct material	Microcuries
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	10
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30 through 34 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person who possesses byproduct material received or acquired prior to September 25, 1971 under the general license then provided in § 31.4 of this chapter is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30 through 34 of this chapter to the extent that such person possesses, uses, transfers, or owns such byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987]

32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.

An application for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

§ 32.19 Same: Conditions of licenses.

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material."

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material—Not for Human Use—Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

[35 FR 6428, Apr. 22, 1970]

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 17 1994

MEMORANDUM FOR: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

FROM: Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: REQUEST FOR RULEMAKING--EXEMPTION FROM LICENSING OF CERTAIN PRODUCTS CURRENTLY COVERED UNDER SPECIFIC OR GENERAL LICENSES

The Commission, on August 13, 1990, in a Staff Requirements Memorandum (SECY-90-175), advised the staff that it concurs with the staff's recommendation to proceed with rulemaking to establish separate exemptions for certain devices which are currently used under specific or general licenses. However, the Commission indicated that the staff should incorporate its proposal into the Below Regulatory Concern (BRC) implementation plan. Since initiation of the BRC policy program has been suspended and the Enhanced Regulatory Participation program is currently being developed, the Office of Nuclear Material Safety and Safeguards (NMSS) request that the Office of Regulatory Research (RES) proceed with this rulemaking as an independent action.

Enclosure 1 includes a first draft of proposed changes to 10 CFR Parts 30 and 32. The changes would exempt persons from licensing for possession, use, transfer and disposal of certain devices. We believe the requirements for either a specific or general license concerning possession, use, transfer and disposal of the devices is excessively burdensome considering the devices pose little or no potential for causing a significant exposure. We request that RES obtain the services of a contractor to examine the effects of the exemptions and ensure adequate protection of people and the environment.

The proposed changes would provide an exemption from licensing to certain users of electron capture detectors, X-ray fluorescence analyzers, static eliminators, static monitors, beta backscatter gauges and calibration and reference sources, which meet certain design and safety criteria. This would relieve the users of the reporting, record keeping, testing and disposal requirements associated with use of the devices under specific or general licenses, and would relieve persons using the devices under a specific license from additional technical and financial burdens. These burdens are not necessary given the low hazards associated with the devices. The change would require an amendment to 10 CFR Part 32 to impose adequate requirements on the vendors of the products.

To assist RES in developing the rulemaking package, we are providing a draft justification for rulemaking (Enclosure 2) and a list of the approximate number of devices currently used by general licensees which would qualify for the exemption based on activity (Enclosure 3).

Attachment 4

One item not addressed in the draft proposed changes is a grandfather clause. We request that RES have a contractor examine the effects of exempting persons using devices that fall in the general category but do not meet all of the design criteria listed in the rule. If a grandfather clause is not appropriate, the statements of consideration for the proposed rule should address that existing devices could be modified to meet the requirements of the proposed exemption.

We request that RES assign a high priority to the rulemaking.

I would like to appoint John W. Lubinski as the NMSS point of contact for the rulemaking. If you have any questions concerning this letter or its enclosures, you can contact Mr. Lubinski at 415-7868.

Original signed by
Carl A. Mazzolo

Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

DISTRIBUTION:
SCDB r/f
SSSS Staff
IMNS Central Files
NMSS r/f
NMSS Dir Office r/f

*See previous concurrence

OFC	SCDB* E	SCDB*	E	SCDB	E	DD:IMNS		D:IMNS	
NAME	JLubinski/tk	SBaggett		RBaer		EWBrach		CPaperiello	
DATE	8/08/94	8/08/94		8/9/94		8/ /94		8/15/94	

OFC	DD:NMSS		D:NMSS	
NAME	CArlotto		RBernero	
DATE	8/17/94		8/ /94	

C = COVER E = COVER & ENCLOSURE N = NO COPY

G:\Beckjord.ltr

One item not addressed in the draft proposed changes is a grandfather clause. We request that RES have a contractor examine the effects of exempting persons using devices that fall in the general category but do not meet all of the design criteria listed in the rule. If a grandfather clause is not appropriate, the statements of consideration for the proposed rule should address that existing devices could be modified to meet the requirements of the proposed exemption.

We request that RES assign a high priority to the rulemaking.

I would like to appoint John W. Lubinski as the NMSS point of contact for the rulemaking. If you have any questions concerning this letter or its enclosures, you can contact Mr. Lubinski at 415-7868.

Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

DISTRIBUTION:
SCDB r/f
SSSS Staff
IMNS Central Files
NMSS r/f
NMSS Dir Office r/f
J. Pierce

OFC	SCDB	SCDB	SCDB	DD:IMNS	D:IMNS
NAME	JLubinski/tk	SBaggett	RBaer	EWBrach	CPaperiello
DATE	8/08/94	8/8/94	8/ /94	8/ /94	8/ /94

OFC	DD:NMSS	D:NMSS
NAME	GArlotto	RBernero
DATE	8/ /94	8/ /94

C = COVER E = COVER & ENCLOSURE N = NO COPY

G:\Beckjord.ltr

ENCLOSURE 1
PROPOSED CHANGES

§ 30.21 Certain devices containing small quantities of byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution certain devices containing byproduct material, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in parts 20 and 30-36, 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires such devices provided that the devices have been initially transferred in accordance with a specific license issued pursuant to § 32.30 of this chapter, which license authorizes the initial transfer of the devices for use under this section.

(b) Any person who desires to initially transfer devices for use pursuant to paragraph (a) of this section, should apply for a license, pursuant to § 32.30 of this chapter, which states that the device may be transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations for an Agreement State.

§ 32.30 Distribution of certain devices containing small quantities of byproduct material.

(a) An application for a specific license to initially transfer devices for use pursuant to § 30.21 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirement of § 30.33(a)(2) and (3) do not apply to an application for a license to transfer devices manufactured, processed, or produced pursuant to a license issued by an Agreement State;

(2) The NRC has issued a registration certificate pursuant to § 32.210 of this chapter and such registration specifies that the design of the device is

appropriate for distribution pursuant to this section.

(3) The device is designed and manufactured:

(i) such that it does not contain more than 20 mCi of Ni-63, 50 mCi of Cd-109, 40 mCi of Fe-55, or 200 mCi of Po-210, or the sum of the quantity of each isotope divided by the quantity set forth in §30.71, Schedule B for each isotope does not exceed 10[1].

(ii) for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or the byproduct material is used for internal calibration or standardization of the device.

(iii) such that the byproduct material is contained in a source housing which cannot be opened without destroying the mechanism designed to seal the housing;

(iv) such that a rod 0.25" (0.635 cm) in diameter by 6" (15.24 cm) in length cannot be inserted into any aperture in the source housing and contact the sealed source used in the device; and

(v) such that the device would maintain its integrity and the radiation levels around the device would not be substantially increased after the device is subjected to the following tests:

Temperature. The device is held at -40°C (-40°F) for 20 minutes and then held at a temperature of 180°C (365°F) for 1 hour.

External Pressure. The device is subjected to an external pressure of 3.6 pounds per square inch absolute (24.82 pascals).

Impact. A 50 g (1.8 ounces) steel hammer, 2.5 cm (0.98 inch) in diameter, is dropped from a height of 1 m (3.3 feet) on to the device. The device is then dropped 10 times to a steel surface from 1.5 m (4.92 feet).

Vibration. The is subjected to a vibration from 25 to 500 Hz at a 5 g peak amplitude for 20 minutes.

Puncture. A 1 gram (0.04 ounce) hammer and pin, 0.3 cm (0.1 inch) in diameter, is dropped from a height of 1 m (3.3 feet) onto the

---

[1] The contractor would need to assist in the determination of the maximum activity of Po-210 allowed to be used in the devices.

device.

The Commission may require the device to survive more stringent testing if the foreseen uses of the device are likely to subject the device to harsh environments.

(4) The device is manufactured and distributed in accordance with a quality assurance program which assures that the quality control standards approved by the Commission are implemented.

(5) The applicant submits sufficient information relating to the:

(i) Degree of access of human beings to the device during normal handling and use.

(ii) Total quantity of byproduct material expected to be distributed in the device annually.

(6) The applicant demonstrates that the radiation exposures which result from the distribution of this device will be as low as practicable.

(7) The device is not used for frivolous purposes or in toys or ornaments.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the device cannot be reasonably foreseen.

§ 32.32 Same: conditions of licenses issued under § 32.30; labeling.

Each person licensed under § 32.30 shall:

(a) Label or mark each device and its point-of-sale package on its external surface with a durable, legible, easily visible label or marking containing:

(1) The following statement: "THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.30. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.";

(2) The name of the radionuclide and quantity of activity;

(3) An identification of the person licensed under § 32.30 to transfer the device for use pursuant to § 30.21 of this chapter or equivalent regulations of an Agreement State; and

(4) The model number of the device as listed on the distribution license.

§ 32.33 Same: records and material transfer reports.

Each person licensed under 32.30 shall maintain records and file a report to the NRC Document Control Desk with a copy to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington; DC 20555, with copies to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(a) The report must include the following information on products transferred to other persons for use under § 30.21 of this chapter or equivalent regulations of an Agreement State -

(1) the quantity of each model device distributed; and

(2) the quantity of activity of each radionuclide contained in each device.

(b) The licensee shall file the report within 30 days following -

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized pursuant to the license issued under § 32.26.

(c) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (b)(1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.30 during the reporting period, the report must so indicate.

(d) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

ENCLOSURE 2

DRAFT

JUSTIFICATION FOR RULEMAKING: EXEMPTING USERS OF CERTAIN DEVICES FROM LICENSING REQUIREMENTS

1. THE ISSUE TO BE ADDRESSED BY THE RULEMAKING AND THE PROBLEM TO BE CORRECTED.

BACKGROUND

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission amended its regulations to provide a general license for the use of byproduct material contained in certain luminous, measuring, gauging, or controlling devices. Under the current requirements for possession of byproduct material under a general license, certain persons may receive and use devices containing byproduct material if the device has been manufactured and distributed in accordance with the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license is issued based upon a determination by a regulatory authority that the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements. The general licensee is required to comply with the safety instructions contained in or referenced on the label of the device and to have the testing or servicing of the device performed by an individual authorized to manufacture, install, or service these devices. A device used under a general license is a "black box," that is, the radioactive material is contained in a sealed source usually within a shielded device. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the general license policy is a mechanism to simplify the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

Other devices which are designed with the same inherent safety features as the devices used under the general license are required to be used under a specific license issued by the Commission or an Agreement State. As such, the user is subject to certain reporting, record keeping, testing, transfer and disposal requirements and, in some cases, additional technical and financial burdens, which are not warranted given the safe design of the device and low activity of the radionuclides.

On August 13, 1990, Staff Requirements Memo (SECY-90-175) required the staff to proceed with rulemaking for exemptions for certain devices currently used under specific or general licenses. This proposed rulemaking was to be in accordance with the Below Regulatory Concern (BRC) implementation program. These certain devices present little or no potential for radiological hazard during possess, use, transfer or disposal. Subsequently, initiation of the BRC program, and the subject proposed rulemaking, has been suspended. However, the subject proposed rulemaking is not part of the BRC policy program and should be continued. The devices to be covered under this proposed rule include electron capture detectors, X-ray fluorescence analyzers, static eliminators, static monitors, beta backscatter gauges, and calibration and reference sources. Currently, users of these devices must either obtain a specific license to possess these devices or use them under a general license. The proposed rulemaking would relieve the users of the reporting, record keeping, testing, transfer and disposal requirements associated with use of the devices under specific or general licenses and would relieve persons using the devices under a specific license from the additional technical and financial burdens. These burdens are not necessary given the low hazards associated with the devices.

ISSUES ADDRESSED

The proposed rule would address relieving users of certain devices containing byproduct material from burdensome cost from licensing requirements which are not justified considering the inherent safety design of the devices. The rule would also relieve NRC and Agreement States of cost associated with licensing the users of the device and some of the cost associated with licensing the manufacturers of the equipment.

With respect to the problem to be addressed, the proposed rule would exempt users of the devices from regulatory requirements based on the design of the devices and the activity of the radioactive material contained in the device.

2. THE NECESSITY AND URGENCY OF ADDRESSING THE ISSUE.

If the rulemaking is pursued, it will allow certain specific and general licensees to use byproduct without having to satisfy existing regulatory requirements. Considering the low potential for radiation exposure associated with the products, the current regulations governing use of the devices covered by this rulemaking is unnecessarily burdensome. Therefore, promulgation of the rule would alleviate the industry of unnecessarily burdensome requirements and would allow NRC and the Agreement States to focus its resources on higher priority issues rather than regulating the possession, use, transfer and disposal of the devices covered by the rulemaking.

3. ALTERNATIVES TO RULEMAKING.

The only alternative to rulemaking is to maintain the status quo. Maintenance of the status quo would continue to impose burdensome specific and general licensing requirements on industry and the would require NRC to continue to expend resources to regulate the possession, use, transfer and disposal of certain devices that pose little or no threat to public health and safety or to the environment. Therefore, the proposed rulemaking is the only viable alternative to addressing the possession, use, transfer and disposal of the devices.

4. HOW THE ISSUE WILL ADDRESSED THROUGH RULEMAKING.

10 CFR Part 30 will be amended to provide an exemption from licensing for the possession, use, transfer and disposal of certain devices containing byproduct material. The exemption is based on the fact that the design of the device is such that it will pose little or no threat to people or to the environment.

10 CFR Part 32 will be amended to provide the specifications that the devices used under the exemptions in 10 CFR 30 must meet to be considered safe.

5. HOW THE PUBLIC, INDUSTRY, THE STATES, AND NRC WILL be AFFECTED BY THE RULEMAKING, INCLUDING BENEFITS, COSTS, OCCUPATIONAL EXPOSURE, AND RESOURCES.

The rule has the potential to result in four distinct benefits. The first is the financial savings to users of the devices in both NRC and Agreement States. Persons currently using the devices under specific or general licenses would no longer be subject to costs associated with license requirements which include reporting, record keeping, testing, performing inventories, and cost associated with transfer and disposal of the devices.

The second benefit would be to the distributors of the devices, located in both NRC and Agreement States. They too would no longer have to adhere to certain license conditions and would not have to provide certain services nor provide certain information to their customers upon transfer of the devices. However, the distributors would incur a one time cost of applying for an exempt distribution license which would allow for the distribution of devices to persons exempt from licensing under the new rule.

The third benefit would be to the Agreement State programs. They would no longer incur costs associated with specifically or generally licensing persons who could be exempt from licensing requirements under the rule change. In addition, certain distributors of devices would terminate their distribution licenses and obtain an NRC exemption distribution license. Therefore, the Agreement State would save the costs associated with maintaining the distribution licenses.

The final benefit would be to NRC. NRC would no longer incur the costs associated with specifically or generally licensing persons who could be exempt from licensing requirements under the rule change and certain distributors would convert their current distribution licenses to exempt distribution licenses. Inspection and enforcement of the exempt distribution licenses would cost NRC less because there are less requirements on the licensees. The number of NRC distribution licensees would increase as a