

DEC 6 1984

MEMORANDUM FOR: Regional Administrators

Branch Chiefs
Division of Fuel Cycle and Material Safety

FROM: Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety

SUBJECT: POLICY AND GUIDANCE DIRECTIVE FC 84-22;
WHAT SOURCE AND DEVICE DESIGNS REQUIRE AN EVALUATION

There have been questions raised concerning the need for review of certain source and/or device designs by the Material Certification and Procedures Branch (FCMC). The questions specifically referred to: (1) calibration and reference standards (2) sources or devices used in research and development, (3) sources or devices used by broad licensees, and (4) custom sources or devices. This directive provides guidance regarding evaluation for these types of sources and devices.

1. Calibration and reference sources may be licensed without review by FCMC if the sources do not exceed the following:
 - o For beta and/or gamma emitting material - 100 microcuries or ten times the quantity specified in Section 30.71, Schedule B, 10 CFR 30, whichever is greater.
 - o For alpha emitting material - 10 microcuries.

The above values were chosen because they represent minimal hazard to public health and safety. To license these sources, identify the isotope in Item 6 of the license, use the statement "calibration or reference sources" in Item 7, and state the maximum quantity for each source in Item 8. Both possession and distribution may be authorized.

2. Source or devices containing sources that are intended only for research and development use need not be sent to FCMC if the applicant is qualified by training and experience to use and handle the requested quantity of material in unsealed form (for sources) or in unshielded form (for registered sources). You may license the source or device without evaluation by FCMC.

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3. Source or devices containing sources to be used by a broad licensee need not be sent to the FCMC if the licensing reviewer has made a determination that the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form (for sources) or unshielded form (for registered sources). In most cases the reviewer need only check if the requested source activity is within the licensee's possession limit.
4. Sources or devices containing sources built to the unique specifications of a given user (custom) need not be sent to the Material Certification and Procedures Branch for evaluation if: (a) they contain less than 200 millicuries of radioactive material or less than 20 curies of tritium, and (b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form. Thus, the applicant would not have to rely on the intrinsic safety of the source or device to demonstrate compliance with 10 CFR 30.33. Custom source and devices which contain an activity greater than that listed above should be submitted to FCMC for evaluation.

To license these custom source and/or devices, identify the isotope in Item 6 of the license, use the statement "custom source" or "sealed source" including drawing or model number, if possible, in Item 7 and state the maximum quantity of radionuclide per source or device in Item 8. In Item 9 (authorized use) describe, as clearly as possible, the actual use of the custom source or device. Examples: "For use in a Model A analyzer custom-built for the licensee by ABC Company in Notown" or "Custom source for use in XYZ Model 100 gauge."

Several questions have arisen regarding whether identical "off-the-shelf" devices with limited distribution can be reviewed as custom devices. This has been a particular problem with imported devices. We will evaluate the first device as a custom device if distribution is anticipated to be limited. FCMC will consider additional identical devices on a case-by-case basis. In general, we will strongly encourage registration of off-the-shelf devices to avoid repetitive custom reviews.

Licensing Reviewer Note:

The NRC normally requires that all sources and devices containing sources be properly evaluated, be found acceptable for licensing purposes, and be registered prior to routine distribution to American customers who would be specifically licensed. The exceptions are discussed in

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this memorandum. Once registered, the license applicant need only identify a specific device and radioactive source by manufacturer and model number when making application for a specific license for possession and use of the device.

Additionally, the NRC requires, as a condition precedent to obtaining registration, that a foreign applicant establish an address in the United States at which will be kept all records required by Commission regulations and at which the registrant specifically authorizes the Commission to serve upon the registrant all papers and legal documents in connection with the Commission's regulatory program.

An applicant must describe how any device is to be serviced. It is preferable that a licensed distributor be established in the United States who is responsible for providing service and maintenance of the device. However, the license applicant may propose an equivalent alternative as to how service is to be performed on the device.

The authorization to use sources or sources contained within devices, which have not been evaluated by FCMC as described in Items 2, 3 and 4 above, apply to use by the applicant only. Therefore, the applicant should not be authorized to distribute the sources or sources contained within devices to other licensees.

All cases referred to FCMC should follow the procedures in Policy and Guidance Directive FC-84-5 dated May 16, 1984.

If you have any questions, please contact Steven Baggett at FTS 427-9005.

Original Signed By

D. R. Chapell

Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

DISTRIBUTION

SBaggett/BSinger
NMSS r/f FC Central File
FCMC r/f JGlenn, RI
BMallett, RIII
JPotter, RII
JEverett, RIV
RThomas, RV
DChapell GDeegan
RE Cunningham EHeumann
RBrightson

*See Previous Concurrence

OFFICE	FCMC *	FCMC*	FC ML*	FC	FC		
NAME	SBaggett/sc	BSinger	VLMiller	DRChapell	RE Cunningham		
DATE	12/4/84	12/4/84	12/5/84	12/6/84	12/6/84		

ROUTING AND TRANSMITTAL SLIP

Date

1 July

TO: (Name, office symbol, room number, building, Agency/Post)

Initials

Date

1. Steve

2.

3.

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

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Phone No.

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CONVERSATION RECORD

TIME

DATE

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TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ANN RAKES

ORGANIZATION (Office, dept., bureau, etc.)

USAF
ISOTOPE COMM

TELEPHONE NO.

SUBJECT

AE-23D-3 CHEM DETECTOR

ROUTING

NAME/SYMBOL INT

SUMMARY

? WHAT AE LICENSE IS THE ABOVE ON?

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

Mayer

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE