

June 15, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

Jesse L. Funches
Chief Financial Officer

William M. Beecher
Director, Office of Public Affairs

FROM: Annette Vietti-Cook, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-99-108 - PROPOSED RULE: [10 CFR PARTS 30, 31, 32, 170, AND 171](#)
- "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING
BYPRODUCT MATERIAL"

The Commission has approved publication of the proposed rule in the Federal Register for a 75-day public comment period. The comments and changes noted below and in the attachment should be incorporated in the rulemaking package, the Congressional letters, and the press release, as appropriate, prior to publication of the draft rule.

(EDO/OPA)

(SECY Suspense: 8/20/99)

The Commission has approved the plan to assess a flat fee to the registrants based on the average cost of the program per licensee. However, the FR notice should be modified to highlight the fee structure. The FR notice should be revised to discuss the other two fee options considered by NRC - a fee per device or sliding scale. Moreover, the FR notice would benefit from a fuller discussion of the basis for the staff's preferred approach as is provided in sections 4.1.J. and 6.0 of the draft Regulatory Analysis.

(EDO/CFO)

(SECY Suspense: 8/20/99)

The Commission has agreed with the staff's plan not to implement a national database at this time. However, the FR notice should be modified to discuss the pros and cons of implementing a national database and request specific comments on this issue. The staff should keep abreast of changes in Agreement State programs that might make them more amenable to a national database. The staff should not delay development of the automated registration system pending outcome of this issue. Instead, this should be handled as a modification to the system, if necessary, after a final decision.

Consideration should be given to requiring taxpayer identification numbers for general licensees subject to registration. If it is not feasible to include this in the current development of the registration system, consideration should be given to adding it at some future time when other system enhancements are needed.

Issues concerning design of generally licensed devices and limitations on the types and quantity of devices that may be used under the general license should continue to be handled separate from this rulemaking since these issues are being reviewed as part of the current Materials Risk Study.

Attachment: [As stated](#)

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

ATTACHMENT

Changes to the Federal Register Notice

1. The Conference of Radiation Control Program Directors represented by Dr. Lipoti raised certain important issues that should be considered. Specifically, 1) the need for a backup responsible individual, 2) the need for additional

- guidance on the use of generally-licensed devices, including safety instructions and response to accidents, and 3) the need for a requirement for up-front disclosure by suppliers or vendors of the devices, including a signed acknowledgment by the purchaser. With regard to 1, the FR notice should be revised to solicit comment on whether general licensees should be required to identify a "*backup responsible individual*" in addition to the "primary" responsible individual. This approach may help ensure that institutional memory is not lost, particularly in cases where the primary responsible individual departs abruptly. With regard to 2, Draft NUREG-1556, Volume 16, should be modified to include additional guidance on safety instructions and precautions that need to be provided to general licensees. The instructions should include limitations on use of the device, instructions for testing the device, response to failures or accidents, and methods for disposal. With regard to 3, the rule should be revised to clearly indicate that full disclosure of the required information should occur *prior to purchase* rather than prior to transfer of the device and the FR notice should explicitly solicit comment on this issue.
2. The staff should consider duplicating all the questions in the FR notice into a single, new section while retaining the questions in their current locations so as to leave them in context. This approach will facilitate the public review and comment process and is consistent with that used in the FR notices for the proposed rules on Parts 35 and 63.
 3. The discussion on page 9 regarding registration of general licensees when the NRC fails to contact needs to be revised. If NRC fails to contact a general licensee, it is unclear how NRC can expect to place the burden of not registering on an uninformed licensee who, even under the current rule, has had little or no contact with NRC. While the Commission supports a provision that would require general licensees to complete registration by a certain time frame, the Commission does not necessarily support NRC taking enforcement action against a general licensee who, once discovered, may have previously violated the registration provision unknowingly because NRC failed to contact them. It should be recognized that there will likely be a subset of existing general licensees who will never be contacted by NRC or an Agreement State because their existence is not known. The staff should make appropriate changes to the enforcement procedures to address this concern.
 4. On page 7, paragraph 1 under 'Discussion', line 6, revise the sentence so it reads ' The NRC also needs to track ~~specific~~ **individual** generally licensed devices'
 5. On page 9, lines 2 and 3 from the top, revise the sentence so it reads ' ... under the general license would bear the **operational** cost of the program instead of those who hold specific licenses.'
 6. On page 9, line 3 from the top, add a new sentence at the end of the paragraph which reads: "However, it should be noted that the initial program startup costs would be recovered from the annual fee paid by current holders of specific licenses."
 7. On page 16, 2nd full paragraph, lines 1 and 2, change the sentence to read ' ... currently restricts applicability **of the general license**, in the case of devices from distributors in Agreement States , to those **devices** from **Agreement States** ~~who~~ **that** authorize the devices to be used'
 8. On page 16, 2nd full paragraph, lines 3 - 7, replace the two sentences which read 'To accommodate the ... by § 31.5 general licensees.' with 'However, NRC practice is to allow a device to be used under the general license in § 31.5, that is distributed in accordance with a license issued under equivalent regulations to § 32.51 by an Agreement State that does not authorize devices to be used under a general license within their State.'
 9. On page 27, line 1, insert 'to two years' after 'limit' so it reads ' Would limit **to two years** the amount of time'
 10. On page 35, in the paragraph under 'Regulatory Flexibility Certification', line 5, insert 'Portions of' at the beginning of the new sentence so it reads ' **Portions of t** The proposed rule would'
 11. On page 45, in item (15), line 1, change the 2nd 'that' to 'than' so it reads 'May not hold devices that are not in use for longer than ~~n~~ **2** years.'

Changes to the Congressional Letters

1. In paragraph 1, line 5, insert 'to certain categories of general licensees' after 'fee' so it reads ' ... use under a general license and (b) add a registration fee **to certain categories of general licensees.**'
2. In paragraph 1, line 5, replace 'this' with 'a' so it reads 'NRC plans to institute ~~this~~ **a** registration system'

Changes to the Press Releases

1. On page 2, paragraph 2, line 4, add at the end 'and, in some cases, have ended up in the public domain' so it reads ' ... generally licensed devices have not been properly handled or properly disposed of **and, in some cases, have ended up in the public domain causing radiation exposures or radioactive contamination.**'
2. On page 3, 1st full paragraph, line 1, insert at the beginning of the sentence 'On March 9, 1999 (64 FR 11508)' and

delete 'has' so it reads ' **On March 9, 1999 (64 FR 11508) t** The Commission has established an interim'