October 23, 1998

MEMORANDUM TO: William D. Travers
Executive Director for Operations

Anthony J. Galante
Chief Information Officer

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-98-199 - PROPOSED RULE:10 CFR PART 31 -- "REQUIREMENT FOR THOSE WHO POSSESS CERTAIN INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIALS TO PROVIDE REQUESTED INFORMATION"

The Commission has approved publication of the proposed rulemaking for 10 CFR Part 31.5 with the changes indicated in the attachment.

(EDO) (SECY Suspense: 11/20/98)

The staff should provide the Commission with its best estimate of the schedule and milestones necessary to complete the automated registration system once the business case has been completed and reviewed by the Information Technology Business Council, and the recommended alternative has been approved by the EC (if the project cost is over $500K) or the CIO (if the project cost is less than $500K).

(EDO) (SECY Suspense: 1/20/99)

The staff should continue to work closely with the Office of the Chief Information Officer (OCIO) to ensure that the automated registration system is developed in a timely manner. In order to control the costs of the automated system, the staff should critically evaluate the program needs. In evaluating alternatives, the staff should explore options such as commercial-off-the-shelf registration software and registration software available from the States or other government agencies that would be sufficiently capable of meeting the basic information capture, recording, and response requirements of the device registration program. The OCIO should ensure that resources devoted to the CPIC analysis are "scaled to the size and complexity of the proposed IT investment" and do not impose "an undue burden on the NRC program staff" (as discussed in SECY-98-032).

Full implementation of the registration program should commence no later than deployment of the automated registration system. In the interim, the staff should take the following steps to address potential safety significant situations. Since the staff plans to forward the proposed rule to affected general licensees for information purposes, the staff should plan to "screen" any information received as a result of this mailing. Specifically, the staff should make available resources to triage the incoming information based on its safety significance, establish simple criteria for determining when, and what type of, follow up action is commensurate with the potential public health and safety risk associated with the device, and perform limited scope inspections when indicated. Follow up activities could range from a simple telephone contact to a limited scope inspection to confirm source identification, location and disposition. Disposition of the information collected in such follow up activities should also be based on its safety significance. This process does not have to be an elaborate one but is intended to identify those situations that, from a public health and safety perspective, warrant action. To complete this approach, the staff should consider developing the interim enforcement policy prior to the final rule-as currently planned by the staff-in the event that there is a need to "grant amnesty" in a specific situation identified as a result of the initial mailing to general licensees discussed above. Regardless of when the interim enforcement policy is implemented, the staff's plan should remain in effect through one complete cycle of the registration program. Also, the Federal Register should be revised accordingly.

Regarding the second more comprehensive rule -- the staff should involve the Conference of Radiation Control Program Directors and Agreement States early in the rulemaking process by sharing the draft rule language at the earliest opportunity and including Agreement State and non-Agreement State representation on the Part 31 rule-writing team. This approach will help ensure timely resolution of such key issues as additional device labeling requirements and compatibility.

Attachment:

As stated

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

PDR
DCS

Editorial Changes to Attachments to SECY-98-199

Changes to the Federal Register Notice:

1. On page 1, paragraph 1, line 2, change 'use' to 'possess.'

2. On page 4, first full paragraph, line 3, insert 'exposure' after 'radiation.'

3. On page 8, after item 3, insert a new item as follows: '4. The location of the devices.'

Changes to the Regulatory Analysis:

1. In page 15, in item 4.2, line 1, add an 's' to 'result.'

2. On page 21, first full paragraph, lines 4-5, delete the remainder of the sentence after 'devices.'

3. On page 24, last paragraph, line 3, delete the 's' on 'licensees.'

Changes to the Congressional Letters:

1. In paragraph 1, line 3, replace 'add an explicit requirement' with 'explicitly require.' In line 4, replace 'provide NRC with' with 'respond to NRC requests for.' In lines 5-6, delete 'as requested by NRC.' In the last line, add 'that are primarily used in commercial and industrial applications' after 'radionuclides'.

2. In paragraph 2, add a new first sentence as follows: 'NRC has observed a number of instances in the past where generally-licensed devices have not been properly handled or disposed of.' In line 2, insert 'there by' after 'and.'

Changes to the Press Release:

1. On page 1, paragraph 1, line 1, insert 'in Part 31' after 'regulations.' In line 3, delete the first 'the.'

2. On page 1, paragraph 3, line 6, insert 'unnecessary' before 'radiation.'

3. On page 2, paragraph 2, line 1, insert 'certain' before 'general.' Add a new sentence to the end of the paragraph as follows: 'About 6,000 general licensees possessing about 24,000 devices will come under the registration requirement.'