



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

July 11, 2000

OFFICE OF THE  
SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM:        SECY-00-0106

TITLE:                    FINAL RULE: 10 CFR PARTS 30, 31, AND 32 -  
"REQUIREMENTS FOR CERTAIN GENERALLY  
LICENSED INDUSTRIAL DEVICES CONTAINING  
BYPRODUCT MATERIAL" AND RELATED  
CHANGE TO THE ENFORCEMENT POLICY

The Commission (with all Commissioners agreeing) approved the subject final rule as noted in an Affirmation Session and recorded in the Affirmation Session Staff Requirements Memorandum (SRM) of July 11, 2000.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette Vietti-Cook  
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc:     Chairman Meserve  
       Commissioner Dicus  
       Commissioner Diaz  
       Commissioner McGaffigan  
       Commissioner Merrifield  
       OGC  
       EDO  
       PDR

## VOTING SUMMARY - SECY-00-0106

### RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	6/23/00
COMR. DICUS	X				X	6/12/00
COMR. DIAZ	X				X	6/1/00
COMR. McGAFFIGAN	X				X	6/26/00
COMR. MERRIFIELD	X				X	6/19/00

### COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were affirmed in an Affirmation Session as reflected in the Affirmation Session SRM issued on July 11, 2000.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook  
Secretary of the Commission

FROM: CHAIRMAN MESERVE

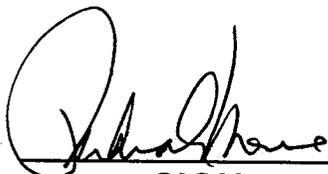
SUBJECT: SECY-00-0106 - FINAL RULE: 10 CFR PARTS 30, 31, AND  
32 - "REQUIREMENTS FOR CERTAIN GENERALLY  
LICENSED INDUSTRIAL DEVICES CONTAINING  
BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE  
ENFORCEMENT POLICY

Approved XX w comments        Disapproved        Abstain       

Not Participating        Request Discussion       

COMMENTS:

See attached comments.

  
\_\_\_\_\_  
SIGNATURE

Jun 23, 2010  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No

COMMENTS OF CHAIRMAN MESERVE On SECY-00-0106

I approve the notice of final rulemaking and the related revisions to the enforcement policy, as described in SECY-00-0106, subject to the following comments.

- I support the views of Commissioners Dicus, Diaz, and Merrified for staff to 1) change the compatibility category for Agreement States for all of 10 CFR 31.5 to Compatibility Category B and 2) change the compatibility category for Agreement States for 10 CFR 31.6 to Compatibility Category B. Modification of the Federal Register notice and the Regulatory Analysis will be necessary.
- I support the views of Commissioners Dicus and Merrifield for staff to 1) report back to the Commission, after a specified period of time implementing this new rule and its registration system (e.g., one to two years), to provide its experiences and recommendations for a national database and 2) report back to the Commission, as soon as reasonably possible, on expediting the process of electronic transmittal by distributors of quarterly reports and other data.

AFFIRMATION VOTE

RESPONSE SHEET

2000 MAY 17 AM 9:25

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER DICUS  
SUBJECT: **SECY-00-0106 - FINAL RULE: 10 CFR PARTS 30, 31, AND 32 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE ENFORCEMENT POLICY**

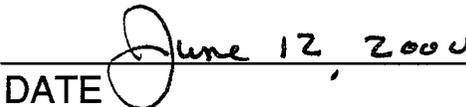
Approved  Disapproved  Abstain

Not Participating

COMMENTS:

See attached comments.

  
SIGNATURE

  
DATE

Entered on "STARS" Yes  No

**COMMISSIONER DICUS' COMMENTS ON SECY-00-0106:**

Let me first state that I strongly support the staff's initiatives and continued hard work in providing the Commission a well-balanced and thorough proposal for a final rulemaking that I believe significantly improves the accountability of generally licensed sources and devices. As the staff is well aware, there has been much attention directed by international safety organizations and national authorities at the potential radiation and environmental hazards associated with lost or misplaced sources and devices. Ensuring that radiation and environmental safety is consistent with societal expectations is a challenge to all concerned and I am pleased to be involved with one of the first agencies to make these proposed changes final as another step in ensuring the public's health and safety. This is a final rule that I heartily endorse and offer the following comments for consideration.

First, I recommend that Compatibility Category B be required for §§31.5(c)(13) and 31.6. As the staff so clearly indicates in the rulemaking package, there are significant transboundary implications associated not only with 10 CFR Section 31.5, but for specific requirements for registration (§§31.5(c)(13) and 31.6). While it is commendable that the NRC give flexibility to States that already have regulations in place for generally-licensed sources and devices, I believe that it is necessary, because of these transboundary implications, that Compatibility Category B be required. In addition, I note that if there ever is hope for a national database in this arena, the assignment of Category B is a step in the right direction.

As to the issue of a national database, I would ask that the staff be prepared to report back to the Commission, after a specified period of time implementing this new rule (e.g., one to two years), to provide its experience and recommendations for a national database.

Finally, I strongly recommend that the staff expedite the process of electronic transmittals of the quarterly report data to allow distributors to transmit this, as well as other reporting information electronically. This will not only to ease the burden of distributors, but should require significantly less NRC staff and contractor support, as well. In an era of paperless transactions, and in an agency strongly supportive of electronic media, I would request that the staff report back to the Commission on this issue as soon as reasonably possible.

Once again I highly commend the staff for their efforts and for succinctly addressing one of many important health and safety issues facing the Commission today.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-00-0106 - FINAL RULE: 10 CFR PARTS 30, 31, AND 32 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE ENFORCEMENT POLICY**

Approved  *hw* Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

See attached comments.

--REC'D BY HJD--

17 MAY 00 9:22

*hw*  
\_\_\_\_\_  
SIGNATURE

*June 1<sup>st</sup>, 2000*  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_

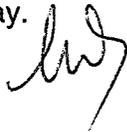
**COMMISSIONER DIAZ'S COMMENTS ON SECY-00-0106: FINAL RULE:10 CFR PARTS 30, 31, AND 32 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE ENFORCEMENT POLICY**

I continue to believe it is necessary for NRC to ensure that general licensees can ensure appropriate handling of and be accountable for their devices. I also believe that this rule is an efficient and effective mechanism for achieving this objective. Therefore, I approve the notice of final rulemaking and the revision to the enforcement policy with the following comments.

I agree with the staff's proposal that the general license requirements should be a Compatibility Category B for Agreement States. However, I disagree with the proposal that the section dealing with the registration requirements, 10 CFR 31.5(c)(13), be a Compatibility Category C for Agreement States. Allowing registration requirements to be Compatibility Category C could lead to 32 different sets of registration requirements. I believe that the transboundary implications associated with both distribution and general licensees' accountability of devices are sufficient to support Compatibility Category B for the rule in toto. Consistent regulations are necessary to ensure that distributors provide general licensees with complete and accurate information about all of their licensing requirements, including registration requirements. The main purpose of registration is to improve general licensees' accountability of devices. Allowing Agreement States to implement different registration requirements, possibly covering types of devices different than those included in 10 CFR 31.5(c)(13), could lead to different levels of assurance of accountability. This could result in lost devices, due to less stringent registration requirements in one jurisdiction, being in the public domain of another jurisdiction. Therefore, all of 10 CFR 31.5 should be a Compatibility Category B for Agreement States.

I also disagree with the proposal that the general license for servicing of devices, 10 CFR 31.6, be a Compatibility Category C for Agreement States. Specifically, this provision grants a general license for distributors to install and service devices used by general licensees. Since these activities are essential to the distribution and safe use of the devices, I believe that this regulation has significant transboundary implication. Therefore, 10 CFR 31.6 should be a Compatibility Category B for Agreement States.

The staff has noted that it needs to obtain OMB clearance for the registration form before registration can begin. The staff estimates that this process will take about 6 months. Therefore, the staff should initiate the first round of registration within 6 months of Commission approval of this final rule. If implementation needs to be delayed, the staff should notify the Commission of the reasons for the delay.

A handwritten signature in black ink, appearing to be 'LDZ', is located below the final paragraph of text.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER MCGAFFIGAN  
SUBJECT: **SECY-00-0106 - FINAL RULE: 10 CFR PARTS 30, 31, AND 32 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE ENFORCEMENT POLICY**

Approved   X   <sup>w/comment</sup> Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

Please see attached comment and edits to FRN.

Edward M. McGaffigan  
SIGNATURE  
June 26, 2000  
DATE

Entered on "STARS" Yes   X   No \_\_\_\_\_

**Commissioner McGaffigan's Comments on SECY-00-0106**

I gladly join my fellow Commissioners in approving the notice of final rulemaking to Parts 30, 31, and 32, to improve the control and accountability of certain generally-licensed devices and the related enforcement policy. I also commend the staff for their efforts to address this important program area which has implications nationwide. I offer the following comments for the staff's consideration.

I fully agree with my colleagues' comments that the compatibility designation for the requirements in 10 CFR 31.5(c)(13) and 31.6 should be changed from category C to B due to the significant transboundary implications associated with use of these devices. I also agree that the staff should keep the Commission periodically informed of the status of this program including such milestones as: 1) when the registration process has been implemented; 2) the staff's experience in establishing and using the national device database and the degree to which Agreement States are compatible with the rule; and 3) the staff's progress in allowing for electronic transmittals of required information. The Commission should also be notified if, during development of the FY 2001 fee rule, the estimated fee changes dramatically (e.g., >25%).

A brief discussion should be added to the *Background* section for the purposes of defining the term, "Agreement State" and identifying the Agreement States since this rule affects general licensees who historically may not have been aware of the distinction between NRC's jurisdiction and that of the Agreement States and may work in both jurisdictions.

I encourage the staff to promptly develop and distribute the pamphlet, briefly discussed in the Federal Register notice, that will provide basic information for general licensees to further increase the likelihood of compliance with this rule.

Finally, I offer the attached edits to the Federal Register notice for clarity.



4. The Commission seeks comment on how best to achieve and enforce the intent that full disclosure of information required to be provided to general licensee customers by distributors be made early enough to be considered in a decision to purchase. For example: Would it be better to use the words, "prior to purchase" in the regulatory text?

Comment: Some commenters objected to the possible use of the words "prior to purchase." Some expressed the concern that "prior to transfer" would not be adequate to achieve the objective. Most commenters talked about the importance of achieving the objective of disclosure before decision, without commenting on the best approach. A couple of the commenters wanted written acknowledgment that the information had been received and read before transfer. However, a couple of the distributors thought it was unreasonable and less effective to require information to be provided prior to transfer instead of at transfer.

Response: The Commission believes the words, "prior to purchase," <sup>is unnecessarily restrictive</sup> presents more ~~problems~~ than "prior to transfer." Although providing information with the device at the time of transfer <sup>not always</sup> may <sup>a few</sup> in some cases get it to the person actually using the device, <sup>prior to transfer of the device is</sup> this will not always be the case. The Commission believes that overall, upfront disclosure ~~will be~~ preferable. The general licensee personnel considering the purchase should see the requirement for appointing a "responsible individual," and, if they purchase the device, will have to provide the distributor the name of the person appointed. ~~Being knowledgeable about this appointment, one should reasonably be expected, in most cases, to provide the information on regulatory requirements to the person appointed to be knowledgeable of regulatory requirements.~~ <sup>unclear + somewhat redundant</sup> The final rule also allows ~~some~~ flexibility to the distributor to use another approach to disclosing <sup>e.g. the</sup> information, if approved by the Commission. <sup>for example,</sup> If the distributor believes that providing some of the detailed regulatory text at the time of transfer would be more effective for his customers, he may

Therefore, the final rule requires that the required information regarding the device be provided 73 to the purchaser "before the device may be transferred."

Comment: One commenter believed that the civil penalties proposed for the loss or unauthorized disposal do not reflect real safety implications, stating that, in the case of polonium-210 (Po-210), the safety hazard involved is minimal.

Response: As explained in the statement of considerations for the proposed rule, the change to the base civil penalty amounts for loss or unauthorized disposal of a sealed source or device will better relate the size of the civil penalty to the costs avoided by the failure to dispose of the source in an authorized manner. While safety implications are an important consideration, a licensee should not receive an economic benefit by committing a violation. A separate notice, published elsewhere in today's *Federal Register*, establishes the new civil penalty amounts and gives a more complete explanation. *The penalties range from \$5,500 to \$45,000.* X

Comment: One commenter suggested that the NRC was creating a new class of license. The commenter stated that although a license is not required, there are still several requirements the user has to meet before getting the device, that in essence there are additional prerequisites that must be accomplished by the vendor (distributor) and end user before receiving the device. The commenter also stated that many of these prerequisites are going to be difficult to demonstrate compliance.

Response: General licenses are established in various Parts of Title 10, Code of Federal Regulations. Some convey only after certain requirements, such as registration, are fulfilled; others convey automatically. In some cases, general licensees must obtain NRC-licensed materials only from distributors who are specifically licensed to supply them. The practical effect of this restriction is that distributors who wish to supply materials to general licensees must obtain a specific license to do so, and must meet certain NRC requirements. Thus, the Commission does not see this rule as creating a new class of license. Where licensees are required to "demonstrate compliance," such as by maintaining records, that requirement is

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

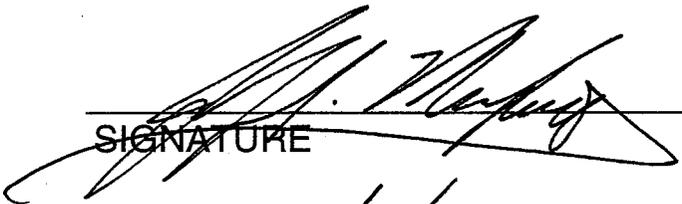
FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-00-0106 - FINAL RULE: 10 CFR PARTS 30, 31, AND 32 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL" AND RELATED CHANGE TO THE ENFORCEMENT POLICY**

Approved  Disapproved  Abstain

Not Participating

COMMENTS: *see attached comments.*

  
\_\_\_\_\_  
SIGNATURE  
  
\_\_\_\_\_  
DATE *6/19/00*

Entered on "STARS" Yes  No

**COMMISSIONER MERRIFIELD'S COMMENTS ON SECY-00-0106:**

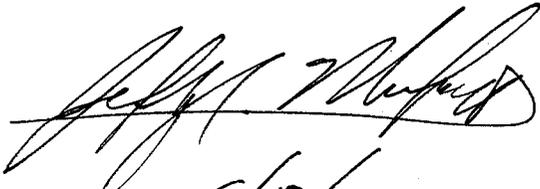
I approve the notice of final rulemaking along with the related revisions to the enforcement policy as described in SECY-00-0106 with the following comments.

First, I believe the requirements in §§31.5(c)(13) and 31.6 should be compatibility category B. There are significant transboundary implications associated not only with 10 CFR 31.5, but also for specific requirements for registration contained in §§31.5(c)(13) and 31.6. In addition, if there is ever hope for a national database in this arena, the assignment of compatibility category B for these sections is a step in the right direction.

SECY-00-0106 mentions that the staff will consider developing a national database after experience is gained with the new registration system. SECY should track staff reporting back to the Commission with its experience and recommendations for a national database within a reasonable time frame (approximately two years or less) after the registration system is implemented.

I strongly recommend that the staff expedite the process of electronic transmittals of the quarterly report data to allow distributors to transmit this quarterly data, as well as other reporting information electronically. The staff should report back to the Commission on this issue as soon as reasonably possible.

Finally, I commend the staff for their efforts in addressing this issue with the coordination of input from the Agreement States. This is an important issue and the resolution is not necessarily easy to develop or implement. But the staff is doing a credible job with this rulemaking package.

  
6/19/00