

October 23, 1998

COMMISSION VOTING RECORD

DECISION ITEM: SECY-98-199

TITLE: PROPOSED RULE: 10 CFR PART 31 -- "REQUIREMENT FOR THOSE WHO POSSESS CERTAIN INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIALS TO PROVIDE REQUESTED INFORMATION

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of October 23, 1998.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commissioners, and the SRM of October 23, 1998.

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John C. Hoyle  
Secretary of the Commission

Attachments: 1. Voting Summary  
2. Commissioner Vote Sheets  
3. Final SRM

cc: Chairman Jackson  
Commissioner Diaz  
Commissioner McGaffigan  
OGC  
EDO  
PDR  
DCS

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VOTING SUMMARY - SECY-98-199

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACKSON	X				X	9/11/98
COMR. DIAZ	X				X	10/2/98
COMR. MCGAFFIGAN	X				X	9/25/98

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 incorporated into the guidance to staff as reflected in the SRM issued on October 23, 1998.

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## Commissioner comments on SECY-98-199

### Chairman Jackson's comments on SECY-98-199:

I approve the staff's recommendation for publication of the notice of proposed rulemaking. The staff should continue to work closely with the OCIO and the agreement states to ensure that the automated registration system is developed in a timely manner. The staff should provide the Commission with its best estimate of the schedule of the milestones necessary to complete the automated registration system.

### Commissioner Diaz's Comments on SECY-98-199:

I approve the publication of the notice of proposed rulemaking for [10 CFR 31.5](#).

Given the minor scope of this rulemaking, the staff should find ways to finalize the rule before the projected date of July, 1999.

The registration program should be initiated when this rule becomes effective, rather than after the automated registration system is completed. In implementing the registration program, the staff should screen the responses from general licensees and follow up as necessary, commensurate with potential hazards indicated by this information. Additionally, the staff should be prepared to implement the proposed interim enforcement policy when the revised 10 CFR 31.5 becomes effective.

Information generated during the initial phases of registration should be entered into the existing registration system, and transferred to the new system when it is completed. Capturing this data in parallel with developing the automated registration system will have the collateral benefit of providing current information to assist in identifying system performance requirements.

Regarding the development of the automated registration system, I am concerned that the procurement process being pursued is more of a hindrance than a help. By focusing the "right" people on a major information technology proposal, the CPIC process should streamline procurement and ensure that the most cost effective system is purchased with taxpayer funds. In this light, I agree with Chairman Jackson that the staff should provide the Commission with a set of milestones for development of the automated registration system. Further, I agree with Commissioner McGaffigan that the staff should critically evaluate program needs and consider less expensive alternatives to a state-of-the-art system, including the availability of a commercial-off-the-shelf system that would be sufficiently capable to meet the basic information capture, recording, and response requirements of the device registration program.

### Commissioner McGaffigan's Comments on SECY-98-199:

I approve the proposed rule to modify Part 31 for the purposes of explicitly requiring certain general licensees (about 6,000 licensees in possession of about 24,000 devices) to respond to NRC requests for information and I offer the following comments for the staff's consideration.

I am concerned about how long it may take to get the general license (GL) automated registration system in place. I worry about "the development of a state-of-the art (emphasis added) system to replace the current database and support a fully automated registration system." There must be commercial-off-the-shelf (COTS) database software available that would meet most, if not all, of our requirements for dealing with approximately 6,000 licensees and 24,000 devices. COTS software would also be easiest for interface with the States. I am surprised that the estimated cost of the project breaks the \$500,000 threshold for full analysis under the Capital Planning and Investment Control (CPIC) process.

I urge the staff to critically evaluate the program needs and see if there is a less expensive information technology alternative available. To the extent full CPIC analysis is still required, I am concerned that the CPIC process looms so large in the staff's thinking that the staff is unable to predict the implementation date for the automated registration system for the rule before us. I urge the Office of the Chief Information Officer to 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](#)).

Regarding the second more comprehensive rule--I urge the staff to 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.

Regarding the GL program in general--while I support the "developmental" efforts currently underway in parallel-development of two rules, the related guidance and an automated registration system, I am concerned that there are no parallel "implementation" efforts between now and mid-to-late FY 2000. For example, it is my understanding that the staff plans to forward a letter to general licensees informing them of this proposed rule. Undoubtedly, some letters will be returned to NRC due to "addressee unknown," some licensees will notify NRC of a change of address, some licensees will indicate that they no longer possess the device(s) in question, etc. These responses could provide NRC with information that, in certain cases, warrants follow up by the staff. Follow up activities could range from a simple telephone contact to a limited scope inspection to confirm device and source identification, location and disposition. Failing to follow up in cases that potentially involve safety-significant information due to the unavailability of an automated registration system to compile and process that information is not, in my opinion, an acceptable alternative. Therefore, I suggest that the staff be directed to make adequate resources available to triage the incoming information based on its safety significance, establish criteria for determining when, and what type of, follow up action is indicated based on the information received and the potential public health and safety risk associated with the device, and perform limited scope inspections when indicated. Disposition of the information collected during these follow up activities should be based on its safety significance. For example, the information may yield an allegation that would warrant additional follow up, or if the information is administrative in nature it could simply be retained for entry into the existing general license data base or the yet-to-be developed

automated registration system. 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, I agree with the staff's plan that it remain in effect through one complete cycle of the registration program. Also, the *Federal Register* notice should be revised accordingly.

I also suggest edits to the *Federal Register* notice, Regulatory Analysis, letters to Congress and the press release as indicated on the attached pages.