

June 15, 1999

COMMISSION VOTING RECORD

DECISION ITEM: SECY-99-108

TITLE: PROPOSED RULE: 10 CFR PARTS 30, 31, 32, 170, AND 171 - "REQUIREMENTS FOR CERTAIN GENERALLY LICENSED INDUSTRIAL DEVICES CONTAINING BYPRODUCT MATERIAL"

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 15, 1999.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission, and the SRM of June 15, 1999.

Annette Vietti-Cook
Secretary of the Commission

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

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

VOTING SUMMARY - SECY-99-108

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACKSON	X				X	5/6/99
COMR. DICUS	X				X	5/9/99
COMR. DIAZ	X				X	4/22/99
COMR. McGAFFIGAN	X				X	4/30/99
COMR. MERRIFIELD	X				X	4/28/99

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 June 15, 1999.

Commissioner Comments on SECY-99-108

Chairman Jackson

I approve publishing the proposed rule that will establish a registration program for certain generally-licensed devices containing byproduct material, and will add provisions to the regulations that will otherwise improve the accountability of generally-licensed devices. In addition, I approve of the plan to assess a flat fee to the registrants based on the average cost of the program per licensee.

The staff should address specifically, during the development of the final rule, certain issues raised in the April 16, 1999 Commission briefing on this subject. First, I recognize that the staff has described certain impediments to establishing a National Database that would include all devices registered by NRC and Agreement States. However, the need to be able to track these devices from state to state outweighs these impediments. The staff should give additional consideration to ways to facilitate the creation of a National Database for these devices.

Second, the Conference of Radiation Control Program Directors represented by Dr. Lipoti raised certain important issues that should be considered in development of the final rule. Specifically, the staff should consider 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 vendors of the obligations of the buyer, including a signed acknowledgment.

I concur with Commissioner Merrifield that consideration should be given to having a taxpayer identification number on the registration form.

Commissioner Dicus

I approve the staff's proposal to publish the proposed rule for public comment subject to the following comments.

1) I have some reservations about whether a flat fee is, in fact, the most appropriate fee structure taking into account fairness and equity considerations for the licensees affected by this proposed rule and cost and other impacts upon the NRC. However, in order to keep the important proposed rulemaking on schedule, I will not, at this time, ask for reconsideration of the staff's proposal in this regard. Instead, the Federal Register notice should be modified to highlight this issue and specifically request comment on it. The Commission may then take these comments into account when it considers final rulemaking.

2) The matter of establishing a National database and compelling Agreement State participation in it as a matter of compatibility is a complex issue. While I will not object, for the purposes of publishing the proposed rule for public comment, to a proposed compatibility category that would permit Agreement States to use their own databases instead of the NRC database, I believe that the Federal Register notice should include a statement that the Commission may decide to require Agreement State use of the NRC database as a matter of compatibility should the National interest show it to be necessary. The Federal Register notice should specifically request public comment on this issue.

I commend staff for preparing a well drafted, timely paper.

Commissioner Diaz

I approve the publication of the proposed rule changes in the Federal Register, including the proposed method of collecting fees to support the program, with the following modifications:

1. 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.
2. The press release should be issued immediately after publication of the proposed rule in the Federal Register and include appropriate reference to the Federal Register.

I appreciate the comments and issues expressed by the representatives of the Steel Manufacturers Association, the American Iron and Steel Institute, the Organization of Agreement States, and the Conference of Radiation Control Program Directors during the April 16, 1999, briefing. The staff should give these comments appropriate consideration during development of the final rule.

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 be handled separate from this rulemaking since these issues are being reviewed as part of the current Materials Risk Study.

The staff has adequately reviewed the pros and cons of a National Database that would include all devices registered by NRC and Agreements States and I support their conclusion to not implement a National Database. Specifically, implementation of a National Database would require Agreement States to adopt 10 CFR 31.5 as a compatibility B regulation. Adoption of 10 CFR 31.5 as a compatibility C regulation, as proposed by the staff, provides an adequate level of assurance of health and safety while allowing the Agreement States sufficient latitude in the development and implementation of accountability programs. This is especially important since some Agreement States already have implemented accountability programs for the general licensees identified in this rulemaking.

The concerns expressed during the briefing about the method of assessing fees and Information Technology (IT) enhancement or development to support the registration program appear to be generic issues that go beyond the general license registration program. Specifically, the method of assessing fees is consistent with the current method of assessing fees for specific licensees and the staff is following the current process and procedures for evaluation and development of the necessary IT needs to support the registration program. Therefore, any changes to these processes or procedures should be handled separate from this rulemaking.

Commissioner McGaffigan

I approve publication of the proposed rule for generally-licensed (GL) devices in the Federal Register (FR) for public comment. I generally agree with the comments of Commissioner Diaz and Commissioner Merrifield and offer the following for the staff's consideration.

Press Release: In addition to the press release suggested by Commissioner Diaz, the staff should also consider issuing a press release on the Commission's decision on this paper, consistent with the staff requirements memorandum on the earlier staff paper on this subject (SECY-97-273).

Fees: Based on fees information provided in the earlier paper and this paper, discussions during the briefing and subsequent information supplied informally by staff in the Office of the Chief Financial Officer, I join Commissioner Diaz in approving the proposal to collect a fee per licensee to maintain the GL program. However, consistent with my vote on the earlier paper, the FR notice should be revised to briefly discuss the other two fee options considered by NRC--a fee per device or sliding scale--and solicit comment on them. 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.J. and 6.O of the draft Regulatory Analysis.

National Database: While a national GL device database has some advantages, I support the staff's current plan not to implement a national database based in part on the disruptive effect that it would have on some Agreement State programs to change the rule compatibility designation from C to B, and the fact that some States may consider the information in the database "proprietary" and thus may be prohibited under State law from entering or using the database thereby limiting its utility. However, as NRC's GL program is implemented, the staff should keep abreast of changes in Agreement State programs that might make them more amenable to a national database at some time in the future.

Taxpayer Identification Number: It has been suggested that requiring registrants to provide their taxpayer identification number may increase NRC's ability to track certain general licensees. The staff should determine the utility of such information and whether it is feasible to modify the registration system at this time--recognizing that this may not be possible since a final decision on the information technology business case is pending--or at some time in the future when other system enhancements are needed.

Backup Responsible Individual: Based on comments by the State representative, Ms. Jill Lipoti, during the briefing, I suggest that the FR notice 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.

Risk Management: While I am sensitive to the concerns raised by the State representatives during the briefing regarding such issues as device design and limitations on types and quantities of licensed material, I agree with Commissioner Diaz that these issues must continue to be addressed separately, consistent with earlier Commission guidance on this issue, so as not to derail the progress being made in the GL program.

Effective Date for Agreement States: While I recognize that the FR notice solicits comment on this issue, I would support decreasing the effective date of the rule for Agreement States from the standard 3 years to immediately effective so as to institute a compatible program nation-wide in a more timely manner and thus further reduce the probability of a GL device inadvertently entering the public domain in an uncontrolled manner.

Draft NUREG: I agree with Commissioner Diaz that the draft NUREG should be revised to include additional safety guidance. This approach would also be responsive to concerns raised by a State representative during the Commission briefing that more information needs to be provided to the purchaser up front so as to further reduce accidents, unintended exposures, and lost or abandoned sources.

Specific Comments on the FR Notice:

1. The discussion on page 9 regarding registration of general licensees the NRC fails to contact is somewhat nonsensical. 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 I generally support a provision that would require general licensees to complete registration by a certain time frame, I do 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.
2. The discussion on pages 22-23 on device information to be provided to general licensees is somewhat unclear as to *when* such information exchange should occur. Specifically, proposed section 32.51(a) requires that certain information be provided to the general licensee *before transfer of the device*. However, the FR notice states that "it is the Commission's intent that 'prior to transfer' would be *before a final decision to purchase* so that the information can be considered in making the purchasing decision. Based on comments by Ms. Lipoti during the briefing, I support revising the rule to clearly indicate that full disclosure of the required information should occur *prior to purchase* of the device. If a majority of the Commission does not support this position, the FR notice should explicitly solicit comment on this issue.
3. 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.
4. More minor editorial changes to the FR notice, press release and Congressional letters are indicated on the attached pages.

Commissioner Merrifield

I approve the staff's request to issue the proposed rule for public comments on a registration program for General License devices as described in SECY-99-108. I have no specific changes that need to be made to the package before it is issued for public comment. There are multiple questions still to be addressed in the implementation of the proposed rule, and it is appropriate to obtain public comments as input to the resolution to these questions. For example, the staff discusses a fee per licensee but then the example provided in the fee analysis assumes a licensee with multiple sites will have a

registration per site. The staff is having difficulty tracking down the location of some licensees, so perhaps additional information, such as a taxpayer identification number, is needed on the registration form. Although I have no doubt that the registration program will improve the accountability and control over general license devices by periodically emphasizing the requirements to the licensees, I do question the ability of the resulting NRC database to efficiently and quickly identify the owner of an orphan source. As currently envisioned, there would be an NRC database and individual databases for each Agreement State. Looking for the owner of a lost source could require searching 30 or more databases. I understand the financial problems of creating a national database and am not advocating a particular solution. However, I want to encourage the staff to continue to seek an innovative solution to the problem. All of the above problems, as well as others, are identified in the proposed Federal Register notice and I believe will be appropriately addressed through seeking public comments.