

POLICY ISSUE INFORMATION

July 24, 2002

SECY-02-0142

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: STATUS OF THE GENERAL LICENSE PROGRAM

PURPOSE:

To inform the Commission about the current status of the General License (GL) Program, and issues that have emerged after the implementation of the registration of certain generally-licensed devices, in response to the July 11, 2000, Staff Requirements Memorandum (SRM) 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" (Attachment 1).

BACKGROUND:

The U. S. Nuclear Regulatory Commission (NRC) established new rules for general licensees in section 31.5(c)(13) of Title 10, U.S. Code of Federal Regulations, which became effective in February 2001. This rule requires general licensees to register devices containing at least 370 megabecquerels (10 millicuries) of cesium-137; 3.7 megabecquerels (0.1 millicurie) of strontium-90; or 37 megabecquerels (1 millicurie) of cobalt-60; or 37 megabecquerels (1 millicurie) of any transuranic element. The new rule was established to increase the control of, and accountability for, generally licensed devices, which supports NRC's Strategic Plan to maintain safety and increase public confidence.

CONTACT: Binesh K. Tharakan, NMSS/IMNS
(301) 415-7138

In March 2001, Version 1.2 of the General License Tracking System (GLTS) was deployed. Version 1.2 of the GLTS allowed NRC to mail out registration forms to the general licensees possessing devices meeting the above registration criteria, and edit information about the general licensees and their devices. Starting in April 2001, the staff mailed out the first annual registration forms, and completed the first round of approximately 3,200 mailings in April 2002.

DISCUSSION:

I. Current Status of the General License Program

Approximately 45% of the 3200 registration forms that were mailed out have been completed and returned (See Attachment 2, Sample Registration Form). The GLTS contractor has begun uploading these into the GLTS. Approximately 15 percent of the registration forms were returned as undeliverable. The remaining 40 percent were not returned. Therefore, 55 percent of the potential first-year registrants (i.e., a general licensee that possesses devices subject to registration) have not responded to NRC. This response rate is significantly less than expected. By performing searches on the Internet, contacting device vendors, and other means, the staff and the GLTS contractor are currently following up on these registrants. Meanwhile, the GLTS contractor continues to routinely enter distribution reports from vendors with an exception discussed later, as well as upload data from registrations that have been completed and returned.

There are three categories of registrants:

1. Registrants whom NRC has not yet been able to contact (undeliverable registrations and registrations not returned);
2. Those registrants that have responded to NRC's request for registration, but have significant discrepancies between NRC data and their own inventory data (e.g., different model numbers, never possessed the device, device whereabouts unknown); and
3. Those registrants that have responded and have successfully registered their devices with NRC.

Despite the poor initial response rate, the staff's goal is to eventually move every registerable general licensee into the third category of registrants.

The staff completed a survey of Agreement State compatibility with the new reporting requirements in 10 CFR 32.52. Compatibility with this section was required by August 16, 2001. Twenty-one Agreement States responded that they have established compatible reporting requirements through legally binding requirements, such as license conditions. Eleven Agreement States responded that they do not have vendors of GL devices. The Agreement States have until February 16, 2004, to establish compatibility with the remainder of the rule changes. Once all Agreement States have adopted compatible rules, the staff will coordinate with the States on implementing a national device database, as mentioned in the SRM. The staff will provide a copy of this information paper to the States.

II. Current Status of the General License Tracking System

As required by the Office of the Chief Information Officer (OCIO), a lessons-learned paper on the development of the GLTS was completed in March 2002. The staff continues to improve the GLTS computer system, through contractor support, to make it more effective and efficient. Version 2 of the GLTS was deployed in March 2002. As a result, registration forms can now be scanned and uploaded directly into the GLTS, and general licensee reported device transfers are more efficiently entered and stored in GLTS.

The previous contractor's poor performance and the transition to a new contractor delayed the deployment of GLTS Version 2.0 by 12 months. To more effectively ensure business software functionality requirements are met, monitor contractor performance, and ensure timely delivery of software products, the staff has:

1. Established a Configuration Control Board (CCB) to oversee changes made to GLTS;
2. To ensure business requirements are fully met, the Office of Nuclear Material Safety and Safeguards (NMSS) has assumed direct oversight of this aspect of the project. OCIO continues to provide technical oversight and is a voting member on the GLTS CCB; and
3. Established an outside contract for Independent Validation and Verification (IV&V) of software. The IV&V contractor has identified several areas where GLTS can be structurally more sound. Future work on the GLTS system will take an IV&V approach in which NRC expectations of quality and audit procedures are made explicit and enforced before deliverables are accepted. These improvements will facilitate future enhancements and maintenance of the GLTS.

III. Issues Associated with the General License Program

Based on experience to date, the staff has identified the following issues:

1. The current fee of \$450 per general licensee was based on an estimate that there would be 4500 registrants to cover the costs of the program. The current estimate is 3200 registrants, primarily because of data corrections and elimination of duplicate records. This decrease in the number of registrants will likely increase the fee per registrant, because of the increased costs for tracking down registrants and some fixed costs which cannot be reduced in proportion to the number of registrants. A summary of the costs for the GLTS and the General License Program is provided in Attachment 3. It should be noted, however, that until the agency can collect the filing fee from the registrants, other materials licensees will continue to pay the costs of the program.

To address this issue of increasing costs, the second round of registration mailings and fee collection has been delayed until early fiscal year 2003 to follow up on missing general licensees, establish a more complete and accurate database with the information received from the first round of registration, and facilitate implementing fee requirements within a future GLTS deployment.

2. NMSS staff is receiving much higher than the expected number of phone calls from general licensees seeking clarification on the registration packets that they have received. Over 1000 staff hours have already been spent responding to about 700 calls.

To address this issue, and to increase general licensees' knowledge of their responsibilities, the staff has completed a website that provides information on the GL Program and registration (<http://www.nrc.gov/materials/miau/miau-reg-initiatives/gen-license.html>). The staff is also preparing supplemental guidance that will be provided to vendors to clarify their reporting requirements and their responsibilities to the end users.

3. The poor response rate to requests for registration indicate a need for additional resources to follow up with general licensees and vendors to determine the disposition of the generally licensed devices. The magnitude of resources needed for this follow-up was not previously budgeted.

To address this issue, the staff is taking the following actions to improve the registration statistics and the follow-up on missing general licensees and their devices:

- i. To reduce the number of registrations that are returned undeliverable, advance phone calls have been made by the GLTS contractor to locate general licensees before sending registration forms to ensure that they are received by the responsible individuals at the correct addresses;
 - ii. A contract is being established with a private investigation firm. This firm will help find general licensees with incorrect addresses. This approach should be more effective and efficient than having the Regions, or the current GLTS contractor, perform this type of follow-up. The private investigation firm will have the specialized skills and experience required to complete these particular types of follow-up; and
 - iii. The staff has modified the budgets for fiscal years 2003 and 2004 to allow for this additional effort.
4. A significant amount of information that is submitted by vendors and general licensees is incomplete or inaccurate. This leads to additional follow-up that was not anticipated. It also indicates a poor level of vendor/general licensee understanding of the requirements.

To address this issue, the staff is preparing supplemental guidance that will be provided to vendors to clarify their reporting requirements and their responsibilities to end users. This guidance will reinforce the device reporting requirements and ensure that vendors are communicating the responsibilities associated with general licenses to the end users before transferring the devices. This effort will be coordinated with the Agreement States.

5. Because of resource limitations, a backlog of data entry exists for generally licensed devices that do not meet the registration criteria. For example, quarterly reports on the transfer of tritium exit signs have not been completely entered into GLTS. The quantity of data and the amount of time required to perform the data entry for these types of generally licensed devices are almost 10 times greater than the time required for registerable

devices. It takes about 80 hours for one person to enter a report from a large exit sign vendor.

To address this issue, and reduce costs, we have temporarily discontinued entry of detailed data for reports from large exit sign vendors. The detailed reports are still available in the Agency-wide Documents Access and Management System. In this interim period, the staff will not have the ability to conduct a rapid search of the database to respond to questions or events involving these devices.

The SRM also required staff to provide an update on the status of electronic transmittals. The staff is considering allowing electronic transmittal of transfer reports and registration forms to further improve the GL Program. The staff is also considering a web-based registration process. These requirements will be considered by the CCB and made part of future releases of GLTS.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:

1. July 11, 2000, Staff Requirements Memorandum (SRM) 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"
2. "Sample Registration Form"
3. "Summary of Costs for GLTS and the General License Program"

IN RESPONSE, PLEASE
REFER TO: M000710A

July 11, 2000

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

John F. Cordes, Acting Director
Office of Commission Appellate Adjudication

FROM: Annette L. Vietti-Cook, Secretary */RA/*

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 1:25 P.M.,
MONDAY, JULY 10, 2000, COMMISSIONERS' CONFERENCE
ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND
(OPEN TO PUBLIC ATTENDANCE)

I. SECY-00-0093 - Rulemaking to Modify the Event Reporting Requirements for Power Reactors in 10 CFR 50.72 and 50.73 and for Independent Spent Fuel Storage Installations (ISFSI) in 10 CFR 72.216

The Commission¹ approved a final rule amending 10 CFR 50.72, 50.73, and 72.216 to: 1) better align the reporting requirements with the NRC's current reporting needs for information to carry out its safety mission, 2) reduce unnecessary reporting burden, 3) clarify the reporting requirements where needed, and 4) be consistent with NRC actions to improve integrated plant safety assessments. The Commission approved the publication and implementation of this final rule subject to the attached changes.

Following incorporation of these changes, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

(EDO)

(SECY Suspense:

8/11/00)

The staff should make the attached changes to the regulatory analysis.

¹ Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Commissioner Dicus was not present when this item was affirmed. Accordingly the formal vote of the Commission was 4-0 in favor of the decision. Commissioner Dicus, however, had previously indicated that she would approve this paper and had she been present she would have affirmed her prior vote.

II. 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

The Commission² approved a final rule amending 10 CFR Parts 30, 31, and 32 to explicitly require general licensees who possess certain devices containing byproduct material to register their devices. The final rule also adds provisions to improve the accountability of generally licensed devices and changes the enforcement policy with respect to the loss, abandonment, or improper transfer or disposal of sources and devices. The Commission approved the publication and implementation of this final rule subject to the attached changes.

Following incorporation of these changes, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

(EDO) (SECY Suspense: 8/11/00)

The staff should initiate the first round of registration within 9 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.

(EDO) (SECY Suspense: 4/11/01)

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

The staff should keep the Commission informed of the status of this program including such milestones as when the registration process has been implemented, the staff's experience in establishing and using the national device database, the degree to which Agreement States are compatible with the rule, and progress in allowing for electronic transmittals of reporting information. Also, the Commission should be notified if, during development of the FY 2001 fee rule, the estimated fee changes dramatically (e.g., $\geq 25\%$).

(EDO) (SECY Suspense: 3/31/01)

The Commission approved the staff's proposed revision to the Enforcement Policy included as Attachment 3 to SECY-00-0106.

² Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Commissioner Dicus was not present when this item was affirmed. Accordingly the formal vote of the Commission was 4-0 in favor of the decision. Commissioner Dicus, however, had previously indicated that she would approve this paper and had she been present she would have affirmed her prior vote.

III. SECY-00-0112 - Hydro Resources, Inc. Petition for Review of LBP-99-18, LBP-99-19, and LBP-99-30

The Commission³ approved a Memorandum and Order: 1) denying review of LBP-99-18, LBP-99-19, and the first half of LBP-99-30 (groundwater); 2) denying the intervenors' motion to reopen the record; and 3) posing questions to the parties regarding the practical import of a recent Tenth Circuit decision.

(Subsequently, on July 10, 2000, the Secretary signed the Memorandum and Order.)

Although the Commission declined to reopen the current adjudicatory record on HRI's Section 8 site, the Commission nonetheless finds that Dr. Fogarty has raised potentially significant generic health and safety concerns that might bear on other sites. Dr. Fogarty maintains, for example, that the NRC's 0.44 mg/l standard is too lenient and that it may expose kidneys to excessive chemical toxicity. The staff should review Dr. Fogarty's submission and take appropriate action.

Attachment:
As stated

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

³ Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Commissioner Dicus was not present when this item was affirmed. Accordingly the formal vote of the Commission was 4-0 in favor of the decision. Commissioner Dicus, however, had previously indicated that she would approve this order and had she been present she would have affirmed her prior vote.

Changes to Federal Register Notice in SECY-00-0093

1. Substitute the following two paragraphs for the third and fourth full paragraphs on page 57 of the *Federal Register* notice.

Spent fuel storage cask problems [former sections 50.72(b)(2)(vii) and 72.216(a)(1), (a)(2), and (b)]. The provisions of section 50.72(b)(2)(vii) are deleted because these reporting criteria are redundant to the reporting criteria contained in sections 72.216(a)(1) and (a)(2). Repetition of the same reporting criteria in different sections of the rules added unnecessary complexity and was inconsistent with the current practice in other areas, such as reporting of safeguards events as required by section 73.71.

Sections 72.216(a)(1) and (a)(2) place upon general licensees the same reporting criteria as are placed on specific licensees under sections 72.75(b)(2) and (b)(3). To avoid duplication in Part 72, sections 72.216(a)(1) and (a)(2) are deleted and section 72.216(c) is abridged to simply require that the general licensee shall make initial and written reports in accordance with sections 72.74 and 72.75. These changes eliminate a reference in section 72.216(a) to section 50.72(b)(2)(vii), now deleted, which had established the time limit for initial notification by general licensees. The same time limit is placed on general licensees by including them within the scope of section 72.75(b). Section 72.216(b) is also deleted because its requirements for a written report are encompassed by section 72.75(d)(2).

2. Page 40, line 16: change "1 hour after the release or notification" to "4 hours of the occurrence"
3. Page 59, line 9: delete "Appendix B, "
4. Page 59, line 17: delete "Appendix B, "
5. Page 59, footnote 3: revise as follows "The examples refer to those published in ~~the November 9, 1999 revision to NUREG-1600.~~ **NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions," dated May 1, 2000.**"
6. Page 63, line 5: change "790" to "700"
7. Page 63, line 10: change "200" to "132"

Changes to Regulatory Analysis in SECY-00-0093

1. Page 2, 'Proposed Action' section, line 3: change "21,000" to "20,800";
line 12: change "14,300" to "13,770" and change "140" to "132";
line 18: change "2 significant digits" to "the nearest 1000 hours or \$100,000";
line 20: change "2 significant digits" to "the nearest \$100,000"
2. Page 3, Table 1: change "150,000" to "148,000" and change "130,000" to "127,000"
3. Page 3, Table 2: change "11" to "11.5" and change "9.8" to "9.9"
4. Delete footnote 4.

Changes to the final rule in SECY-00-0106

1. The compatibility category for Agreement States for 10 CFR §§ 31.5(c)(13) and 31.6 should be changed from Compatibility Category C to B.

Changes to the Federal Register Notice in SECY-00-0106

2. The staff should add a brief discussion 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.
3. On page 73, paragraph 3 (Response), revise line 1 to read ‘ ... to purchase,” **is unnecessarily restrictive and** presents more’
4. On page 73, paragraph 3 (Response), in line 2, add a new sentence after the period which reads ‘**Therefore, the final rule requires that the required information regarding the device be provided to the purchaser “before the device may be transferred.”**’
5. On page 73, paragraph 3 (Response), revise lines 3 and 4 to read ‘ ... transfer may, in **a few** some cases, **not always** get it to the person actually using the device, **this will not always be the case.**—~~T~~ the Commission believes that overall, upfront disclosure **prior to transfer of the device is** ~~will be~~ preferable.’
6. On page 73, paragraph 3 (Response), in lines 7 through 9, delete the 5th sentence (Being knowledgeable about this ... regulatory requirements.)
7. On page 73, paragraph 3 (Response), revise line 10 to read ‘ ... allows ~~some~~ flexibility to the distributor to use another approach to disclose ~~ing~~ **the** information,’
8. On page 73, paragraph 3 (Response), revise line 11 to read ‘ ... by the Commission. **For example,** if the distributor believes’
9. On page 77, paragraph 2 (Response), add a new sentence to the end which reads ‘**The base civil penalties range from \$5,500 to \$45,000.**’

ATTACHMENT 2

SAMPLE REGISTRATION FORM



GL-3816-01
01/15/2002

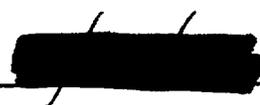
SECTION 5 - CERTIFICATION

SECTION 5
PAGE 1 of 1

I hereby certify that:

- A. All information contained in this registration is true and complete to the best of my knowledge and belief.
- B. A physical inventory of the devices subject to registration has been completed, and the device information on this form has been checked against the device labeling.
- C. I am aware of the requirements of the general license, provided in 10 CFR 31.5.
(Copies of applicable regulations may be viewed at the NRC web site at www.nrc.gov/NRC/CFR/index.html)





SIGNATURE - RESPONSIBLE INDIVIDUAL (Listed in Section 1)

DATE

WARNING: FALSE STATEMENTS MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL ASPECTS. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY WRONG STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER IN ITS JURISDICTION.





GL-3816-01
01/15/2002



SECTION 6 - DEVICES NOT SUBJECT TO REGISTRATION

SECTION 6
PAGE 1 of 1

NRC Device Key:

Manufacturer License No:

Manufacturer Name:

Model Number:

Serial #:

Transfer Date: 00/00/0000



Summary of General License Tracking System (GLTS) Costs

Fiscal Year	Costs for GLTS Development	Costs for GLTS Maintenance
1999	\$164,514	GLTS under development
2000	\$515,039	GLTS under development
2001	\$479,675*	\$235,837
2002		\$204,695
2003		\$125,000 (projected)
2004		\$125,000 (projected)
Total cost through April 2002	\$1,159,228	\$440,532

*GLTS Version 1 was accepted in March 2001 (development completed). \$258,663 of \$479,675 was spent to acquire high-powered servers (hardware) to increase efficiency for production, development, and testing.

Summary of General License Program Costs

Fiscal Year	Implementation and Operation Costs of the General License Program
1999	\$0*
2000	\$320,690
2001	\$460,628
2002	\$288,803
2003	\$790,000 (budgeted)
2004	\$790,000 (budgeted)
Total cost through April 2002	\$1,070,121

*Implementation of the new General License Program did not begin until fiscal year 2000.