SECRETARY

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

May 3, 2013

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0071

TITLE: FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL - AMENDMENTS/INTEGRATED SAFETY ANALYSIS (RIN 3150-AI50)

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of May 3, 2013.

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

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-12-0071

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	1/29/13
COMR. SVINICKI		X			X	2/11/13
COMR. APOSTOLAKIS	X	X			X	1/11/13
COMR. MAGWOOD		X			X	10/12/12
COMR. OSTENDORFF	X				X	7/2/12

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane

SUBJECT: SECY-12-0071 – FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL – AMENDMENTS/INTEGRATED SAFETY ANALYSIS (RIN 3150-A150)

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __X__ None ___

SIGNATURE

1/29/13

DATE

Entered on "STARS" Yes __X__ No ___

Chairman Macfarlane's Comments on SECY-12-0071
"Final Rule: Domestic Licensing of Source
Material-Amendments/Integrated Safety Analysis"

I approve issuing the proposed rule to require certain source material licensees to perform integrated safety analyses (ISA). I would like to thank the staff for the effort that was put into this rulemaking package. This was not an easy rule to develop, even with Part 70 as a guide, and I appreciate the hard work.

When it was first written, Part 40 was not intended to cover large complex enrichment or conversion facilities. The 1961 Federal Register notice constituting "...an over-all revision of 10 CFR Part 40." was barely four pages long. Those four pages contained the entire body of Part 40 regulations. It did not include any mention of byproduct material, enrichment, construction, decommissioning, uranium mill tailings, or financial assurance. The main focus of the regulation was to regulate source material from a strategic quantity perspective. It is clear that the regulation was not written to cover conversation or deconversion facilities such as Honeywell or International Isotopes[1]. Through numerous amendments, Part 40 has been revised and expanded over the years. The current rule now covers 58 pages in the Code of Federal Regulations. Even with this significant expansion, the rule continues to need improvement.

In 2010, the Commission recognized this need and requested that the staff develop this rulemaking to improve Part 40 and require the performance of an ISA similar to that required by Part 70[2]. The regulatory analysis for the rulemaking states that the current Part 40 does not provide structured risk-informed requirements for evaluating the consequences of facility accidents. The intent of this rulemaking is to establish this risk informed framework and to provide NRC with increased confidence in the safety of these facilities. The Commission paper cites numerous Commission decisions, task force reports, and analyses that have shown the need to make improvements to Part 40. To address these concerns this rulemaking establishes clear limits on and definitions of adverse consequences; requires licensees to protect against these adverse consequences; requires licensees to report radiological or chemical exposures to workers and the public in a timely fashion; imposes change management requirements; requires inclusion of the safety basis with the license application; requires additional worker training; and requires identification of items relied on for safety and measures to ensure that they are available when needed. These actions significantly improve Part 40 and are needed to address the issues previous identified by the staff.

I understand my colleagues' concerns with ISA and the differences from probabilistic risk assessment (PRA). I agree that NRC should continue to consider ways to incorporate probabilistic risk assessment into our regulatory approach for engineered systems. However, this rulemaking establishes a risk informed framework that is a great improvement from the current situation. This and the other significant improvements contained in the rule should not

[1] Honeywell Metropolis Works, Metropolis, Il; International Isotopes Fluorine Products Inc., Hobbs, NM
[2] SRM – M070308B dated March 22, 2007

be delayed as we further consider the issue of how to apply PRA, a lengthy process which could take years to complete. The regulatory analysis lists 19 serious incidents that that have occurred at fuel cycle facilities involving radiological or chemical hazards[3]. We need to approve these changes to Part 40 as soon as possible to reduce the likelihood of these types of events happening in the future.

With regard to the performance measures contained in the rule, they are protective and appropriately consistent with the Part 70 criteria as directed by the Commission. When the Commission approved the Part 70 revisions it determined that 100 rem to the worker and 25 rem to a member of the public are high-consequence events. The Commission also determined that measures must be put in place to protect against such events occurring. These determinations remain unchanged. The performance requirements should continue to contain the Commission's definition of high-consequence events to ensure consistency for future Part 40 facilities. Just as conversion facilities were not envisioned in 1961, we do not know what types of facilities this regulation will cover 20 years from now.

I agree with Commissioner Magwood about the importance of interaction and communication with the States. The changes the staff made to the final rule package as a result of stakeholder comments show the importance of stakeholder engagement. This is especially true for the Agreement States. Agreement States have valuable perspectives and experience. They need to be cognizant of proposed rulemakings and decisions that the staff are considering early enough in the process so they can have meaningful input.

I also agree with Commissioner Ostendorff that the staff should publish relevant guidance at the same time as the issuance of the rule. Licensees should have all necessary guidance documents available to them at the time the NRC expects them to begin developing their ISAs.

In conclusion, limited budgets and resources will always require us to make choices and priorities. The staff has spent considerable time and effort on this rulemaking, which is a positive step forward. We cannot waste the valuable resources we have expended in developing this rule by delaying it. The staff should issue the rule and continue to consider ways to incorporate PRA in the future.

1/29/13

Allison M. Macfarlane Date

[3] 10 CFR Part 40 Integrated Safety Analysis (ISA) Final Rule Regulatory Analysis, dated April 2012, p. 3.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-12-0071 – FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL – AMENDMENTS/INTEGRATED SAFETY ANALYSIS (RIN 3150-A150)

Approved ____ Disapproved __XX__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __XX__ None ___

SIGNATURE

02/11/13
DATE

Entered on "STARS" Yes ✓ No ___

Commissioner Svinicki's Comments on SECY-12-0071
Final Rule: Domestic Licensing of Source Material –
Amendments/Integrated Safety Analysis (RIN 3150-A150)

I disapprove publication of the draft final rule at this time and return the matter to the staff for additional consideration of select issues. I share the concern of Commissioners Apostolakis and Magwood that the staff has not substantively evaluated whether integrated safety analysis (ISA) is the most appropriate tool for oversight of 10 CFR Part 40 licensees. The quality and depth of ISAs, resulting from their graded application at licensee facilities and the flexibility of our guidance documents and licensing process, varies widely. I agree with Commissioner Magwood that the agency's experience with ISAs at 10 CFR Part 70 facilities does not appear to have been fully factored into the development of this draft final rule and that revised draft final guidance related to the rule should be made available to the Commission to inform a decision on the approval of any draft final rule. For example, in the absence of criteria for determining the adequacy of an emergency plan for licensees required to have such a plan, important aspects of the implementation of the draft final rule cannot be assessed. Further, the staff has not informed the Commission of how NRC would approach the application of ISAs in the absence of the American Nuclear Society standard for ISA use, the development of which the Commission only recently directed the staff to undertake in concert with external stakeholders. The staff should provide an information paper to the Commission describing the issues that have been encountered during the implementation of the ISA rule imposed on 10 CFR Part 70 licensees and how these implementation issues have been addressed in a way to avoid their occurrence at Part 40 licensees, if ISA requirements are imposed for that category of licensees.

I note that the State of Washington and the Organization of Agreement States expressed concerns that they were not given adequate opportunity to engage in the rulemaking process in this instance. The NRC staff traditionally invests significant effort in outreach to States and other regulatory partners, making this critical feedback particularly noteworthy. I am confident the NRC staff will assess whatever circumstances occurred here, both as input to NRC's continuous improvement processes and for application to the further development of the issues associated with this topic.

Kristine L. Svinicki 02/11/13

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-12-0071 – FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL – AMENDMENTS/INTEGRATED SAFETY ANALYSIS (RIN 3150-A150)

Approved _X_ Disapproved _X_ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___

SIGNATURE

1/11/13
DATE

Entered on "STARS" Yes √ No ___

Commissioner Apostolakis' comments on SECY-12-0071
"FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL - AMENDMENTS/INTEGRATED SAFETY ANALYSIS"

I approve the addition of the backfit provision and the rule text that reserves NRC regulatory jurisdiction over all source material at facilities authorized to possess 2000 kg or more of UF6. I disapprove publication of the remainder of the final rule text.

Along with Commissioner Magwood, I question whether the Integrated Safety Analysis (ISA) is the appropriate regulatory tool for the oversight of 10 CFR Part 40 licensees. The quality of ISAs varies among licensees as a result of the flexibility in development of an ISA afforded by the guidance documents and licensing process, as the staff has indicated. Moreover, concerns over the quality of the ISA led the Commission to request development of an American Nuclear Society standard for conducting ISAs for fuel facilities. Unfortunately, this standard will not be available in the near future. Thus, I propose that the staff provide a paper discussing how the ISA would be conducted in the absence of the ANS standard. For facilities authorized to possess 2000 kg or more of UF6, the paper should also explore approaches other than ISAs, similar to Commissioner Magwood's proposal. In addition, the plan should include options to establish risk-informed decision guidelines for these facilities.

I also offer the following comments for consideration.

- Staff's finding that asserting the NRC's licensing and regulatory authority over all future source material facilities authorized to possess 2000 kg or more of UF6, including those facilities located in Agreement States, is justified on the bases of common defense and security should be strengthened. Staff justification broadly applies a very narrow 1987 decision to keep the Honeywell site under NRC jurisdiction when Illinois became an Agreement State. At that time, Department of Energy (DOE) asserted that the uranium conversion facility was essential to national security because it provided UF6 to the DOE enrichment complex for military and energy purposes. In its 2007 letter, DOE did not make such a national security nexus for the licensing and regulation of future facilities in Agreement States. Therefore, staff should strengthen its basis for the common defense and security determination to address future commercial nuclear activities. The staff's revision should be provided to the Commission for review prior to its publication.

- Expand the last paragraph on page 59 of the draft *Federal Register Notice* by adding the following.

  "As indicated by DOE in its letter to the NRC in 1986 (Enclosure 1 to SECY-07-0146), uranium conversion facilities are important to the national security in maintaining a secure supply of nuclear fuel to critical infrastructure facilities. Honeywell's Metropolis facility continues to be the sole domestic supplier of UF6 feed for the nation's uranium fuel cycle industry. DOE in its 2007 letter (Enclosure 4 to SECY-07-0146) supported NRC's decision to regulate these facilities, and that US energy security would be significantly enhanced by additional private sector investment in the domestic nuclear fuel supply."

George Apostolakis
January 11, 2013

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-12-0071 – FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL – AMENDMENTS/INTEGRATED SAFETY ANALYSIS (RIN 3150-A150)

Approved ____ Disapproved __X__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __X__ None ___

GMM

SIGNATURE

12 October 2012

DATE

Entered on "STARS" Yes __X__ No ___

Commissioner Magwood's Comments on SECY-12-0071,
"Final Rule: Domestic Licensing
of Source Material-Amendments/Integrated Safety Analysis"

Since the time the draft of the subject rule was presented to the Commission, the agency has gained additional experience in addressing the safety issues associated with facilities that would be impacted by this proposed rulemaking. This experience has allowed the agency and licensees to review important safety issues in the context of integrated safety analyses (ISAs) similar to the ISAs performed by 10 CFR Part 70 licensees to assess safety and guide agency responses to assessments of plant conditions. This experience has not built confidence in the regulatory approach that relies on the use of ISAs at these facilities.

Staff and licensees have long indicated that ISAs (rather than probabilistic risk assessments, or PRAs) are the appropriate tool to apply to materials facilities because, in large respect, Part 40 facilities are less complex than reactor facilities and accidents at such facilities present a far lower safety risk to the public. They have argued that use of ISAs, which are based on process hazard analyses commonly used in the chemical industry, provide a rough consistency with the assessments performed to assure safety in chemical facilities with similar risk profiles.

This logic was, until recently, compelling. However, it is now clear that Part 40 facilities with ISAs are subject to the consideration of accident scenarios that anticipate the release of their entire chemical inventory into the environment. For facilities with relatively large inventories of potentially hazardous chemicals that are subject to NRC regulation, the consequences of worst-case accidents bare more plausible analog to those of reactor accidents. As a result, despite the commentary provided in SECY-12-0071, I do not believe that PRA approaches to analyze the safety of large Part 40 facilities can be easily dismissed.

Clearly, licensees have resisted a shift to PRAs because of the perceived cost and difficulty of developing PRAs for their facilities. Based on recent experience, I would not be surprised if some licensees might now consider the subject rule to be the path of higher cost and difficulty. From an NRC perspective, I similarly now wonder if PRAs would provide a more effective, predictable, and consistent mechanism for regulating chemical facilities that operate in a nuclear regulatory context. I withhold final judgment on this point, but I do not at this time accept staff's previous arguments on this matter.

The anticipated rule would amend 10 CFR Parts 40 and 150 to require source material licensees possessing more than 2000 kilograms of uranium hexafluoride (UF6) to perform ISAs and to set possession limits for UF6 to determine whether the NRC or Agreement States have licensing authority for a facility. Given the concerns discussed above, I am not now in a position to approve the publication of the subject final rule in the *Federal Register*.

Additional work is required before we can contemplate the publication of this final rule. I suggest the following:

1) Staff should provide a plan through which PRA approaches could be implemented at large Part 40 and Part 70 facilities should the Commission choose to direct the Staff to move forward using PRA. This plan should detail implementation hurdles and costs to the agency and licensees and provide a basis for final Commission decision on this issue.

2) Staff should revise the regulatory analysis provided with SECY-12-0071 to reflect the experience gained since the draft rule was issued. Stakeholder comments soundly rejected the staff's cost analysis and it should be modified to assure that all costs associated with implementing ISAs at Part 40 facilities are captured.

3) Consistent with the comment in Commission Ostendorff's vote, the guidance for this proposed rule should be completed. However, I believe the Commission should receive a draft of this guidance to support a final decision on the rule.

4) It is essential that the performance requirements in the rule (specifically, section 40.81) be modified to state clearly the hazards that a conversion or de-conversion facility would be expected address in an ISA (such as the threshold for soluble intake for workers). Doing so will assist the Commission's consideration of the rule and provide needed clarity and transparency. As currently written, it is not clear how a conversion or de-conversion facility licensed under Part 40 could develop an ISA using the current performance requirements in section 40.81(b) (1) and (2). I note that the current performance requirements address acute worker doses between 0.25 Sv (25 rem) and 1 Sv (100 rem) Total Effective Dose Equivalent (TEDE) and acute doses to members of the public of 0.25 Sv (25 rem) TEDE. It is not possible to have an accident scenario associated with a conversion or de-conversion facility that would produce these impacts, thus it is obvious that other requirements (no doubt based on chemical hazards) must be established.[1]

5) Staff should develop criteria for determining the adequacy of an emergency plan for licensees required to have such a plan as a result of this proposed rule. Staff should clearly identify the nature of the accident sequence licensees are required to evaluate. This can be provided in the guidance. (*Note:* the current guidance in NUREG-1140 concludes that the accident determined to cause the most significant release is the rupture of two 14-ton UF6 cylinders along with a gasoline fire.)

6) Staff should detail in the guidance how licensees with and without current ISAs should transition to the ISAs or PRAs resulting from the publication of this rule.

7) Staff should also provide guidance for existing Part 40 facilities with no baseline design criteria as required in Part 70 on how to address natural phenomena hazards that are considered in the ISA without the requirement to modify their facility to meet the baseline design criteria.

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[1] A review of NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees" states that "the release of UF-6 presents a chemical hazard rather than radiological hazard. Exposure lethal due to uranium chemical toxicity or hydrofluoric acid (HF) burns on the lung tissue would not result in radiation doses exceeding 1 rem effective dose equivalent, therefore radiation does are not calculated. The release assumed is the escape of 9400 Kg of UF-6 in 15 minutes due to the rupture outdoors of heated 14-ton cylinder."

Finally, I am concerned by the comments submitted by OAS and the State of Washington that indicated that at least some states did not believe they were provided adequate opportunity to engage this process. This regulatory issue is complex and states have significant equity in this issue. I strongly urge staff to work very closely with all affected states as this rule is finalized.

Patrick M. Bulwar for 10/12/12

William D. Magwood, IV **Date**

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-12-0071 – FINAL RULE: DOMESTIC LICENSING OF SOURCE MATERIAL – AMENDMENTS/INTEGRATED SAFETY ANALYSIS (RIN 3150-A150)

Approved _X_ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___

_____
SIGNATURE

7/2/12
DATE

Entered on "STARS" Yes _X_ No ___

Commissioner Ostendorff's Comments on SECY-12-0071, "Final Rule: Domestic Licensing of Source Material- Amendment/Integrated Safety Analysis"

I approve publication of the final rule on the domestic licensing of source material which will require, among other actions, that Part 40 licensees possessing significant amounts of uranium hexafluoride complete an integrated safety analysis (ISA). I continue to believe that these requirements will provide for risk informed, consistent, and predictable regulation.

Some commenters on the proposed rule indicated that additional guidance is needed on potential implementation issues such as how to evaluate features inherent to the plant's design ("design features") and the appropriate thresholds for evaluating the consequences of dermal exposures. I understand that the staff is developing guidance on these issues, but that this guidance will not be complete until 2014, which is beyond the date when licensees will be required to submit their ISA summaries. I believe that a full understanding of these issues is necessary for our licensees to effectively implement the rule. In accordance with the Commission's direction in SRM-SECY-11-0032, "Consideration of the Cumulative Effects of Regulations in the Rulemaking Process", the staff should issue the guidance on these issues with the final rule. The staff should explore options, including issuing interim staff guidance or a regulatory information summary, for providing this guidance in a manner that does not significantly impact the timely issuance of the rule.

Commenters also indicated that more discussion may be needed to clarify issues related to application of the rule to Part 70 facilities that also possess material subject to the rule. Given the need for additional guidance and discussion, the staff should provide ample opportunities for discussion of these or any other implementation issues that arise. The staff should keep the Commission informed of its efforts to resolve these implementation issues.