

Rulemaking Comments

From: Evans, Hugh [Hugh.Evans@qsa-global.com]
Sent: Monday, May 12, 2008 4:09 PM
To: Rulemaking Comments
Subject: RIN 3150-A129
Attachments: CORAR NSTS Commentary.pdf

DOCKETED
USNRC

May 13, 2008 (9:00am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dear Sirs,

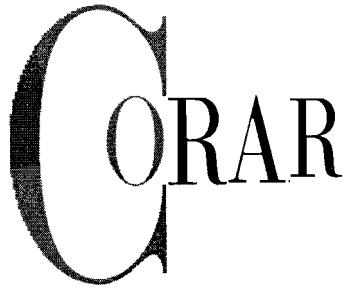
On behalf of the Council on Radionuclides and Radippharmaceuticals (CORAR) I submit the attached Adobe Acrobat file containing comments on the Proposed Expansion of the National Source Tracking System.

Sincerely,

Hugh W. Evans
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Henry H. Kramer, Ph.D., FACNP
Executive Director

May 9, 2008

Secretary,
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attn: Rulemaking and Adjudication Staff

**Subject: Comments on the potential impact of the information collection requirements for the proposed rule relating to the Expansion of the National Source Tracking System
RIN 3150-A129 [NRC-2008-0200]**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

The final rule establishing the National Source Tracking System (NSTS) reflected the IAEA Code of Conduct recommendations that are consistent with the NRC's responsibilities under the Atomic Energy Act, including the protection of the public health and safety. The implementation date for the NSTS has been extended to January 31st, 2009.

The principal purpose of the NSTS is to provide reasonable assurance of timely detection of either the theft or diversion of radioactive materials sufficient to constitute quantities which should be of concern regarding the construction of a radiological dispersion device. This is consistent with the Code of Conduct which is to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources.

We believe that while the implementation of the NSTS to Category 1 and 2 sources may have defined merit, the proposed extension of the NSTS to include Category 3 and 1/10th of Category 3 is significantly flawed, considering:

- i) The IAEA Safety Guide, No. RS-G-19, “Categorization of Radioactive Sources” specifically cites in section 2.3 that “categories should not be subdivided as this would imply a degree of precision that is not warranted and would lead to a loss of international harmonization.”
- ii) The premise that there is potential for aggregation of category 3 sources or even 1/10th of Category 3 to a Category 2 level is not justified and doesn’t support the requirement for extension of the NSTS to Category 3 sources. While the language of the proposed rule consistently refers to “sources”, in reality such an aggregation would only occur on the premises of a manufacturer of sealed sources or a nucleonic device Original Equipment Manufacturer (OEM). These licensees operate under enhanced security conditions and operate in accordance with individual security orders. In the practical deployment of sealed sources they are incorporated within secured, often heavyweight radiological shields that form an integral part of the nucleonic device, so their aggregation, while possible, would entail a considerable engineering impediment.
- iii) The existing licensing demands necessary for the operation of source manufacturing, the registration of nucleonic devices, their distribution, pre-licensing verification, transfers of sources under existing security orders to verify new users and the flagging of significant changes in ordering patterns, licensing of the end-users and the requirement for 6 month leakage tests, provide an existing regulatory environment and data base that allows adequate “safeguarding” of the “sources”. While it is suggested in the proposed rule that “adding such sources to the NSTS would provide for increased accountability for these sources because there would a near real-time knowledge (sic) of source whereabouts and an ability to confirm an individual licensee’s account of their sources” we do not believe that such inclusion would significantly improve on the current accountability. Neither do we understand how extension of the NSTS to Category 3 sources would aid in preventing or indeed enabling the earlier identification of nefarious activities over and above the existing licensing, audits and inspections carried out on licensees by the NRC or Agreement states.
- iv) The significant increase in data records that would have to be accommodated by the NSTS by the potential inclusion of Category 3 and 1/10th Category 3 begs the question as to how the NRC will monitor this data to identify potential nefarious practices? We do not recognize how such a data base can, per-se, assist in the prevention of source aggregation, as envisaged, nor the earlier identification of such potential nefarious activities.

2. Is the estimate of burden accurate?

We do not believe the estimate of burden to be accurate. The estimated burden on licensees is unfounded, as licensees (the users) have not seen a draft version of the database. Without knowledge of how the database works or how it is going to be integrated makes it impossible to assess how much time and effort needs to be expended to use the database for both the initial start up and ongoing day to day usage. An accurate assessment of the burden can only be made once the licensees have viewed the database and experienced how it works.

Further, we believe it is presumptuous and premature for the NRC to extrapolate potential cost burdens for the possible inclusion of Category 3 and 1/10th Category 3 sources when no such system is currently in place for the priority Category 1 and 2 sources (implementation date 31st January, 2009). Stakeholders such as source manufacturers, nucleonic device OEMs and large licensees have had no direct involvement in the NSTS since fall 2006. Additionally no test programs have been trialed nor training given to potential participants.

In 3.2.3.1 of the NRC Draft Report on the Regulatory Analysis for the Proposed Rule on Expanding the NSTS – 10CFR parts 20 and 32 (February, 2008), the NRC estimates that, between 2008 and 2010, the NRC would incur approximately \$0.6 M to expand the IT requirements for the NSTS to Category 3 (\$1.5 M for 1/10th of Category 3).

This estimated cost includes costs for entering new licensees into the NSTS and credentialing new users, including the process of validating users, and providing certificates and hardware tokens. This value represents both NRC staff and contractor time and effort. In addition to initial set-up costs to implement the NSTS, there would also be annual costs to NRC for maintenance and operation of the system. The Regulatory Analysis for the rulemaking for Category 1 and 2 licensees estimated that these annual costs would be approximately \$2.7 M for the 1350 licensees estimated for that system. Based on that analysis, including considerations related to DOE sources, it is estimated that the annual costs for the expanded NSTS, based on the numbers of licensees with Category 3 and 1/10th of Category 3 sources, would be approximately \$2M per year for the addition of Category 3 sources (\$5 M for 1/10th of Category 3 sources) beginning in FY 20104 beyond what is already expended on the existing NSTS.

Further, the “OMB supporting statement for Proposed Rule 10CFR Parts 20 and 32 and NRC Form 748 Expansion of the NSTS (RIN3150-A129) Revision” cites in 14. (page 8) “Estimated Annualized Cost to the Federal Government” an even higher figure for all costs attributed to operating the NSTS. Estimated operation and maintenance cost for expanding the NSTS for the additional sources covered by this rulemaking is \$ 7.7M per year for the first three years and \$7 M thereafter (based on section 3.2.3.1 of the draft Regulatory Analysis,). The first three year cost includes costs to NRC for credentialing of licensees as well as the costs of ADP, record holding, and clerical processing of NRC Form 748. Subsequently, the cost includes only the ADP, record holding, and clerical processing costs.

We do not consider that the supposed benefits of the expansion of the NSTS justify this potential expenditure; in fact we believe that should such a budget be available, then the primary aims of the NSTS would be better served by allocation of such funds to the provision of ensured disposal sites for the secured disposal of sealed sources that are surplus to industry requirements.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

As stakeholder involvement has to date been essentially zero, it is necessarily difficult to advise or comment on enhancement or general quality improvement for a system that has yet to be “declared”. There is significant stakeholder concern at the volume of data potentially required and the lack of present advisories as to the mechanisms of electronic uploading to a central data base.

Particular concern exists at the inclusion of perceived unnecessary data. From the final rule for Category 1 and 2 sources, it was determined that manufacturers have to register two entries, one upon initial manufacture and one upon actual transfer from their premises. This requirement will result in an additional 30% of the total transactions listed. In light of the secure environment

existing at source manufacturers' premises, this requirement reflects an unnecessary burden on the manufacturer and the NSTS data base.

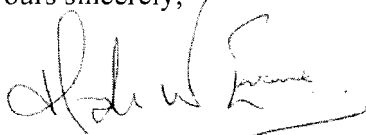
We do not understand how such a reporting requirement assists in accomplishing the primary aims of the NSTS.

4. How can the burden of the information collection be minimized, including the use of automated collection techniques

The estimate of time needed for both NRC and the licensees to reconcile a discrepancy in the day-to-day transfers, is greatly underestimated. In most cases there will be investigations between the user, the transferor and the regulatory authority to resolve such issues. Industry experience in locating potentially missing packages indicates that it takes many hours to accurately track down such occurrences.

We appreciate the opportunity to provide these comments on this proposed rule and shall be glad to provide clarification or additional information if required.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Hugh W. Evans". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Hugh W. Evans
Secretary/Treasurer

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