



American Association of Physicists in Medicine

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May 12, 2008

Mr. Nathan Frey
Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB-10202 (3150-0001, 0014, 0202)
Washington, D.C. 20503

Re: RIN-3150-AI29: OMB Review of NRC Information Collection Requirements and Solicitation of Public Comments on NRC Proposed Rule Regarding Expansion of the National Source Tracking System [*See* 73 Fed. Reg. 19749 (April 11, 2008).]

Dear Mr. Frey:

The American Association of Physicists in Medicine¹ (AAPM) is submits the following comments to the Office of Management and Budget (OMB). AAPM recommends that OMB not approve the revised definition of “nationally tracked source” and corresponding information collection requirements proposed in Sections 10 C.F.R. §§ 20.1003, 20.2207, 32.2 and Appendix E to Part 20. AAPM specifically believes that proposed regulations are at best premature, unnecessary and cannot be justified under the Paperwork Reduction Act.

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.” Based on this, NRC’s decision to propose expansion of the NSTS to Category 3 and 1/10th of Category

¹ The American Association of Physicists in Medicine’s (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

3 sources is inconsistent with the IAEA Code of Conduct, the basis of NRC's decision to design and implement the NSTS for Category 1 and 2 sources.

AAPM submits that the NRC already has the ability to identify licensees that possess Category 3 or 1/10th of Category 3 sources, and to monitor the location and movement of the sources through the licensing and inspection program. AAPM submits that the same end result of the proposed rule could be achieved by NRC via implementation of the latest version of the "pre-licensing guidance" and dedicating adequate resources for an even more rigorous licensing, inspection and enforcement programs to ensure licensee compliance with existing requirements, e.g., 10 C.F.R. § 30.41 without increasing the regulatory burden on the licensees.

Additional comments are provided in the enclosure.

Thank you for the opportunity to comment. Feel free to contact me at 720-854-7515 or via email: dpfeiffer@bch.org or Lynne Fairbent, Manager of Legislative and Regulatory Affairs at 301-209-3364 or via e-mail: lynne@aapm.org if you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas E. Pfeiffer". The signature is written in a cursive style with a large initial 'D'.

Douglas E. Pfeiffer, MS, DABR
Chair
AAPM's Government and Regulatory Affairs Committee

Enclosure

cc: Records and FOIA/Privacy Services Branch (T-5F52), NRC

**American Association of Physicists in Medicine (AAPM) Comments on
Information Collection Requirements in the NRC Proposed Rule
Concerning the National Source Tracking System (NSTS)**

AAPM General Comments:

A. Expanding the Scope of the NSTS at this time is at best premature.

The NSTS for radioactive material in quantities of activity greater than IAEA's quantity of concerns for Categories 1 and 2 has not been implemented. The implementation date for the NSTS has been extended to January 31st, 2009, thus there is currently no inventory system that is operational.

The original scope and purpose of the NSTS was to track, monitor and account for the nationwide use of Category 1 and 2 sources, as defined in the International Atomic Energy Agency's (IAEA) Code of Conduct as the most hazardous sources from a public health and safety perspective. NSTS development and deployment has experienced significant technological delays (years) and increased costs and is not in use today for Category 1 and 2 sources by NRC, much less by the Agreement States or licensees.

Since the original scope of the NSTS was limited to Category 1 and 2 sources, affected licensees (those that only have Category 3 and 1/10th of Category 3 sources) who would be subject to the expanded NSTS rule have had little to no visibility of the system or how the system will actually work. In addition, affected licensees do not have sufficient information or data on which to evaluate and judge the validity, accuracy and completeness of the reporting burden estimated by NRC in the proposed rule. NRC's estimates of licensee burden for certain required actions ranges from 2 minutes per transaction to 20 hours of computer programming, but the source of these estimates contained in the Regulatory Analysis is unclear.

Therefore, AAPM firmly believes that the proposed rule to expand the scope of the NSTS beyond Category 1 and 2 to include much lower risk sources, *i.e.*, Category 3 and 1/10th of Category 3 sources, is at best premature in the absence of a fully functioning NSTS as originally designed and intended. Experience should be gained from the system as originally designed prior to a proposal to expand it. AAPM recommends at least a two year pilot as allowed for by the Paperwork Reduction Act. In addition, AAPM believes the impact will be greater should NRC decide to expand the list of radionuclides beyond those listed in Appendix E to 10 CFR Part 20.

B. The Proposed Requirements Are Unnecessary

The NRC has not provided evidence to suggest that existing requirements and the current regulatory approach to source security is not adequate to oversee licensed activities and ensure public health and safety. Specifically, the NRC and Agreement States have had in place, new guidance for the conduct of additional screening and "pre-licensing" visits during the initial licensing process to further ensure that byproduct material licenses are issued only to legitimate

persons. This guidance was further revised twice in response to the General Accounting Office's (GAO) audit of NRC's licensing process in the spring of 2007 (GAO-07-1038T, dated July 12, 2007).

As such, the regulator's role in, and emphasis on, ensuring that source recipients are legitimate has increased. Also, byproduct materials licensees have been for years and are currently subject to 10 C.F.R. § 30.41, "Transfer for byproduct material." This requirement explicitly describes the licensee's responsibility to ensure that, prior to transfer of generally- or specifically-licensed material, the licensee verify that the recipient is authorized to receive the type, form and quantity of byproduct material to be transferred. Agreement State regulations have comparable requirements in place for their licensees. Also, licensees possessing quantities of certain sources that, in the aggregate, meet or exceed the Category 2 level are already subject to the increased control of sources Orders (and corresponding Agreement State requirements). Thus, there is enhanced tracking, control and monitoring of sources of concern below the Category 2 level.

NRC's statement that it needs to be in a position to monitor the "real-time tracking" of certain sources is unfounded, in that, who better to have such awareness than legitimate licensees whom the regulator has scrutinized prior to licensing and is responsible for overseeing licensee compliance with applicable requirements. As such, NRC's cost estimate of \$7.7 million to initially deploy and operate the NSTS for the first 3 years and subsequent operational costs of \$7 million each year thereafter would be much more effectively spent by applying these resources to existing NRC and Agreement State licensing, inspection and enforcement programs. Expending NRC resources to expand NSTS now also seems counter intuitive to the NRC statement that expansion of the NSTS would "increase public confidence." Specifically, it seems that the public's confidence would likely be increased much more if NRC were to expend these resources on existing NRC and Agreement State programs. Finally, AAPM is somewhat concerned that Agreement State resources, already stretched thin in some States, due to the increased control of sources and fingerprinting requirements imposed by NRC in 2005 and 2007, will be further exacerbated by the need to dedicate resources to implement an expanded NSTS for lower risk sources in the absence of a clear public health and safety basis. Clearly, it is not in anyone's interest—including the public's-- to have scarce regulatory resources diverted from higher risk activities to much lower risk activities.

AAPM offers the following responses to the specific questions in the Federal Register.

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?*

No. As stated in our letter, AAPM believes NRC can accomplish the same goals delineated by this proposed rule if NRC and Agreement States fully implement the latest version of the "pre-licensing guidance" and dedicate adequate resources for an even more rigorous licensing, inspection and enforcement programs to ensure licensee compliance with existing requirements, e.g., 10 C.F.R. 30.41. NRC also states that expanding the NSTS will "improve regulatory knowledge." AAPM believes that there is no demonstrated proof to the NRC's stated concern regarding the "potential" for individuals to accumulate sources in quantities to reach the Category 2 level and believes that the regulator's knowledge would be improved and increased

by dedicating additional resources to its existing regulatory programs, e.g., increased inspection frequency of licensees authorized to possess Category 3 or below sources, rather than requiring more record keeping and reporting to NSTS potentially in lieu of a more “hands on “ approach by the regulator.

2. *Is the estimate of the burden accurate?*

The final rule establishing the National Source Tracking System (NSTS) reflected the IAEA Code of Conduct recommendations. However, since the implementation date for the NSTS (Category 1 and 2 sources) has been extended to January 31st, 2009, even licensees possessing Category 1 and 2 sources do not have the experience to make a sufficient determination of the actual burden of complying with the final rule as published (71 FR 65686). Stakeholders (e.g., source manufacturers, radioactive device Original Equipment Manufacturers and large licensees) have had no direct involvement in the NSTS since fall 2006. Additionally no test programs have been trialed or training given to potential participants for the Category 1 and 2 sources. 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.

For “newly” affected licensees (those who only have category 3 or 1/10th of category 3 sources) that would be subject to the expanded NSTS recordkeeping and reporting requirements, they do not have experience with or sufficient information or data regarding NSTS on which to evaluate the validity, accuracy and completeness of the reporting burden estimated by NRC in the proposed rule (from 2 minutes per transaction to 20 hours of computer programming). Such experience could be gained, however, if NRC terminated this rulemaking and dedicated its resources to deploying a fully functional NSTS for Category 1 and 2 sources and allowed sufficient time (e.g., 2 years) to gain experience with the system, make modifications as indicated, solicited input from licensees and the Agreement States, and then revisit the decision of whether to expand the NSTS to include Category 3 and 1/10th of Category 3 sources. As such, a functioning NSTS for Category 1 and 2 sources could be considered a “pilot program” as allowed by the Paperwork Reduction Act.

The estimated annual cost given in the OMB *Clearance* package for expansion for Category 3 and 1/10th of Category 3 was \$7.7 M each for the first three years and \$7 M every year after that. AAPM does not consider that the supposed benefits of the expansion of the NSTS justify this potential expenditure. AAPM believes that the primary aims of the NSTS would be better served by allocation of such funds to ensuring that disposal sites are available for the secured disposal of sealed sources. This is a significant issue, due to the loss of Barnwell for the disposal of Category 3 and below sources; many small licensees will have no route of disposal resulting in a much more important security concern that needs to be addressed.

AAPM believes that the estimate of time needed for NRC, Agreement States 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. Stakeholder experience in locating potentially missing packages indicates that it

takes many hours to accurately track down and resolve such occurrences.

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

Since stakeholder input to the design of the NSTS has been minimal to date, it is difficult to provide comment on “*a way to enhance the quality, utility, and clarity of the information to be collected.*” In our October 11, 2005 comment letter to the NRC (re: RIN 3150AH48: Public comments on the Proposed Rule for a National Source Tracking of Sealed Sources), AAPM stated that the NRC should “conduct roundtable discussions with stakeholders, to fully understand the impact of rulemaking on the medical community and to ensure that final regulations do not cause problems in the practice of medicine. AAPM would also be willing to survey its members to ascertain the number of sources that would be included should a decision be made to include Category 3 sources.” In addition AAPM recommended that “[t]he NRC should establish a users' group composed of a representative membership of the affected licensees to develop the formats, input means and reports that will be available through the system. This will assure that the system meets the NRC's needs and is also user friendly to the licensees who will input and verify data.” These comments were not acted upon.

AAPM believes that in the absence of a fully deployed NSTS, it is not clear whether there is a way to enhance the quality, utility and clarity of the information to be collected. Experience with collecting the required information on Category 1 and 2 sources in NSTS could yield such insights and is a logical first step to implementing the program. This is particularly true since not only are there more Category 3 and 1/10th Category 3 source licensees (3,500 licensees) than Category 1 and 2 licensees (1,300 licensees) but the number of sources per licensee is likely to be higher due to the nature of their use in medical, academic, industrial and commercial applications.

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

As stated above, only experience with the NSTS will yield such insights and identify necessary modifications to the system to reduce the burden where possible. However, state radiation control programs vary in size and resources and in degrees of electronic documentation of their licenses. AAPM does not believe that the “burden of information collection” has fully accounted for the differences in the licensing process which exist in the various Agreement States. In fact for those states without electronic database systems will have to “manually” review records to identify licensees that are required to participate, thus increasing the regulatory burden.