Enclosure
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. Inconsistency with Proposed Rule for Specific Licenses vs. General Licenses

There are two types of licenses currently issued by the Nuclear Regulatory Commission (NRC) and the Agreement States – specific licenses and general licenses (GL). NRC should not expand the NSTS at this time until the potential for a general licensee – who is not subject to the current or proposed NSTS requirements – to possess and use at least IAEA Category 2 quantities of material is addressed. This issue was discussed at length by NRC staff in SECY-06-0094 and most recently in SECY-07-0147. Also, the Organization of Agreement States and the State of Florida petitioned NRC on related GL program matters and have expressed their support for an overhaul of the GL program regulatory framework on more than one occasion. Radioactive sources of similar radiological risk or hazard should be regulated more uniformly and consistently to more adequately protect public health and safety.

Any effort to revise the existing regulatory framework for GL sources and devices has the potential to result in a rulemaking that would significantly increase the number of specific licenses that would be subject to the NSTS. If this occurs, significant additional ongoing costs would be incurred for NRC and the Agreement States as well as affected licensees nationwide to capture and track those newly designated sources. Therefore, it is premature to expand the NSTS beyond Category 1 and 2 until such time that a comprehensive review of the existing GL regulatory framework is conducted. NRC officials have publicly stated that a proposed GL rule might be available later this year, which supports industry's position to wait until such a rulemaking is well underway if not completed before revisiting the decision of whether to expand the NSTS.

B. 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 concern 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 have 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 familiarity with the system or how it would actually work. In addition, these 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.

C. The Proposed Requirements Are Unnecessary

The NRC has not provided evidence to suggest that existing requirements and the current regulatory approach to source security are 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 of 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, AAPM suggests that it is better to have such awareness derived from 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 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.

D. Stakeholder Input

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.

E. Definition of "Transfer"

The proposed rule states that "[T]hese transactions would include manufacture, transfer, disassembly, receipt, or disposal of the nationally tracked sources." The fundamental understanding of the term "transfer" is critical to complying with this proposed rule. Nowhere is the term "transfer" defined in the proposed or existing regulations. It is unclear whether the movement of a source from one building of the licensee's facility to another building or room within a licensee's facility is a "transfer". This needs to be clarified prior to implementation of the proposed rule.

F. The Proposed Information Collection Requirements Do Not Satisfy the Paperwork Reduction Act

As stated in AAPM's May 16, letter to the Office of Management and Budget in response to this NSTS proposed rule, the Paperwork Reduction Act intends to improve the "responsibility and accountability" of OMB and all other federal agencies to Congress and to the public for reducing the burden of federal reporting and information collection requirements (See 44 U.S.C. 3501(1), (2) (11). The Act criteria include, but are not limited to, "an evaluation of the need for the collection of the information," "a specific, objectively supported estimate of the burden," and a "test of the collection program through a pilot program, if appropriate."

AAPM does not believe that the proposed information collection requirements are necessary for the proper performance of the functions of the NRC or the Agreement States. 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 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. AAPM believes that the regulator's knowledge would be most effectively 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.

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.

G. Specific Comments on the Federal Register Notice

1. 73 FR 19754: NRC states that "Based on its consideration of the comments and of the results of the Regulatory Analysis, the Commission is proceeding with the proposed rule for expansion of the NSTS." This statement implies that a firm agency decision has been made to expand NSTS as described in the proposed rule. However, on the previous page, NRC asks 3 specific questions to gather additional information concerning the number of impacted licensees, number of sources captured by the expanded categories and their activities, as well as information on transactions of these sources. These statements of consideration appear internally inconsistent and raise the question as to the basis for the apparent NRC decision to proceed with rulemaking to expand the NSTS as described in this proposed rule. This NRC request for information compounded with the fact on page 19753 that 12 of 18 previous commenters opposed expanding NSTS, raise serious concerns with the basis of the proposed rule. Also, AAPM is unaware of any specific NRC activity involving licensees or stakeholders, beyond the "one-time" accounting of Category 3 sources, to gather relevant information and better inform the regulatory analysis for the proposed rule.

2. 73 FR 19756: NRC states that it is "interested in determining whether specific requirements for tracking should also be included in 10 CFR Part 110 and specifically invites comment on this question. Without additional detail on NRC's intent with regard to the import and export of these lower risk sources, it is difficult to comment on the need for or type of specific requirement appropriate for imported sources.

H. Specific Comments on the Regulatory Analysis

1. Section 3.1 Identification of Affected Attributes. The first bullet of this section specifies that "[T]his information would provide a life cycle account of these sources." In several public meetings, NRC staff stated that once a Category 2 source decayed below the Category 2 threshold, it would be removed from the NSTS. In addition, this issue is also discussed on page 19757 of the proposed rule. Here it states: "Once a source has decayed below 1⁄10 of Category 3 threshold level, it would no longer be considered a nationally tracked source, and the source would automatically be removed from a licensee's active inventory in the NSTS. The licensee would receive a notification that the source has decayed below the tracking level, and that transactions for this source no longer need to be reported."

In removing this source, there is no life cycle accountability provided. The NRC staff has also stated that the NSTS does not provide "cradle-to-grave" tracking of the source once it has decayed below the threshold for a Category 2 source. The regulatory Analysis should be redone to account for this.

2. Section 3.2.2.1 Number of Licensees that Possess Nationally Tracked Sources. It is unclear from the Regulatory Analysis discussion whether or not the "one time data collection" referenced include a statistically significant sampling of all NRC and Agreement State licensees. If not, then it is difficult to understand how the NRC can perform a "quantitative analysis" on this category of sources. If this data collection has not been conducted in a statistically significant manner, then how did NRC determine the impact provided in this Regulatory Analysis?