PR 20 and 32
(71FR34024)

KELLEY DRYE & WARREN LLP
A LIMITED LIABILITY PARTNERSHIP
3050 K STREET, N.W.
SUITE 400
WASHINGTON, D.C. 20007
(202) 342-8400

NEW YORK, NY
TYSONS CORNER, VA
CHICAGO, IL
STAMFORD, CT
PARSIPPANY, NJ
BRUSSELS, BELGIUM
AFFILIATE OFFICES
MUMBAI, INDIA

FACSIMILE
(202) 342-8451
www.kelleydrye.com

John L. Wittenborn
202.342.8514
JWittenborn@kelleydrye.com

(2)

June 29, 2006

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USNRC

July 10, 2006 (12:50pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Ms. Merri Horn
U.S. Nuclear Regulatory Commission
Attn: Rulemaking and Adjudications Staff
11555 Rockville Pike
Rockville, MD 20852

Re: Proposed Rule for National Tracking of Sealed Sources
(71 Fed. Reg. 34024 (June 13, 2006))

Dear Ms. Horn:

On behalf of the Metals Industry Recycling Coalition ("MIRC")[1], we are pleased to provide you with these comments on the U.S. Nuclear Regulatory Commission's ("NRC's") Proposed Rule for National Source Tracking of Sealed Sources. 71 Fed. Reg. 34024 (June 13, 2006). MIRC also provided comments on the NRC's initial Proposed Rule published on July 28, 2005. 70 Fed. Reg. 43646 (July 28, 2005).

In our previous comments on the Proposed Rule and in testimony provided at the NRC public meeting, MIRC supported the Commission's proposal to implement a National Source Tracking System to monitor and provide increased oversight of certain sealed sources. However, we have urged the NRC to extend the tracking system to include Category 3 sealed sources. Now that NRC is proposing to promulgate the National Source Tracking System ("NSTS") under its authority to protect public health and safety, MIRC believes it is even more imperative to include Category 3 sealed sources in the program because improper disposal of Category 3 sources can pose significant risks to public health and safety even if they are not viewed as significant in terms of a terrorist threat. Accordingly, we again respectfully request that NRC include Category 3 sources in the NSTS.

[1] MIRC is an *ad hoc* coalition of metals industry trade associations and companies comprised of the American Iron and Steel Institute ("AISI"), the Copper and Brass Fabricators Council ("CBFC"), Inco, Inc. ("Inco"), the Nickel Institute ("NI"), the Steel Manufacturers Association ("SMA"), and the Specialty Steel Industry of North America ("SSINA").

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I. Background

Companies that are members of the associations that comprise MIRC play a major role in the U.S. economy. Among other things, they recycle scrap metal to make new metal products. These companies are the largest recyclers by volume in the country.

Each year steel mills operating electric arc and basic oxygen furnaces recycle more than 75 million tons of scrap into new steel products. Steel products contain, on average, 66 percent recycled content. These products have wide ranging applications including many consumer products such as food and beverage containers, automobiles, homes and even surgical implants.

Copper and brass scrap is also widely recycled into a variety of products that go into consumer use. In 2005, the copper industry recycled approximately 1,140,000 tons of scrap into new products. Copper and brass products contain, on average, 50 percent recycled content.

Nickel, a highly valued metal, is recycled at an exceptionally high rate. Nickel not only is recycled as scrap, but also is recovered from waste materials such as used batteries and electric arc furnace ("EAF") pollution control dust. In fact, upwards of 95 percent of the nickel content in stainless steelmaking EAF dust and other wastes can be recovered for reuse in new products.

The recycling of scrap metal has become a sophisticated, technology-based industry, involving highly-controlled scrap selection and blending processes necessary to meet detailed customer specifications, including specifications and certification regarding radioactivity. Recycling generates significant environmental benefits. MIRC members recycle material that otherwise would be discarded in a landfill or improperly disposed. Such recycling conserves significant amounts of energy by using a feedstock of scrap instead of virgin ores. The annual energy savings from the steel minimill industry alone is enough to supply power to the city of Los Angeles for eight years.

Over the past two decades, an industry-wide problem has emerged involving the amount of scrap metal contaminated with radioactive material. Some of this contamination in scrap is the result of background radiation absorbed by steel products, such as oil and gas transmission pipes. A more dangerous and potentially life-threatening form of contamination, however, is the presence of shielded radioactive sources – typically Cs-137 or Co-60 in the scrap supply.

II. Concerns Over Radioactive Sources in the Scrap Feedstock

The sheer number of sealed sources in commerce today, combined with the lack of an effective national oversight program for these sources, too often has resulted in sealed sources being discarded and channeled into the recycling stream for recovery of their metal components.

Radioactive sources in scrap feedstock pose a number of serious problems for the metal recycling industries. A radioactive source that is inadvertently melted in a furnace has the potential to lead to dangerous levels of radiation exposure for mill workers and even the

surrounding community. When a radioactive source is melted, depending on the isotope involved, it may contaminate slag and slag handling equipment, the finished metal product, the furnace, baghouse, duct systems, and the surrounding facility. In one instance in Florida, a teletherapy unit was discovered prior to melting that was rated at 5,000 curies of cobalt-60. Had the unit contained its rated quantity of cobalt-60 and been melted, it would have subjected the melt shop workers and the surrounding community to a potentially lethal dose of radiation. Cobalt-60 was, in fact, melted at a Mexican facility in 1983.[2] The workers and community suffered serious radiation exposure and, unfortunately, the steel was allowed to enter the United States to be used in homes.[3]

In addition to exposure concerns, when a source is melted, each component of the system must be completely cleaned and many mill components must be discarded. Contaminated items must be disposed of in costly low-level radioactive waste disposal facilities. The mill must remain closed while the remediation and replacement takes place. Often this can take several weeks to several months. The combined cost of the remediation, disposal and closure following an inadvertent melt of a radioactive source may easily fall in the range of $12-$24 million.

Since 1980, there have been 84 known melts of significantly radioactive sources by the metals recycling industry internationally.[4] In each case, workers were placed at unnecessary risk and facilities were saddled with substantial remediation and disposal costs, with many being forced to close for extended periods of time. One of these 84 inadvertent melts occurred in Florida in 2001. This facility melted a significant source containing Cesium-137. Fortunately, no employees were subjected to any dangerous exposures. However, the mill was forced to close for 27 days and incurred several million dollars in remediation and disposal costs.

The downstream customers of MIRC member companies are also extremely concerned about radioactivity in recycled metal products. The metals industry has worked diligently for many years to build consumer confidence in the safety and utility of products made from recycled metal. However, the public, often fueled by sensationalized news reports, remains concerned about the safety of recycled metals in products that they use. The mere perception that metal products are unsafe because they are made from scrap metal that is potentially radioactive may lead to massive customer de-selection. Notwithstanding government assurances that the scrap is safe or that low levels of radiation are safe, consumers simply do not want any added radiation in their homes, automobiles or workplaces. Rightly or wrongly, consumer confidence would be severely undermined if even small amounts of low-level radioactive sources were found in the scrap feedstock.

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[2] *Nuclear Security: DOE Needs Better Information to Guide its Expanded Recovery of Sealed Radiological Sources.* GAO-03-483 (Sept. 2005).

[3] *Id.* at 1.

[4] *Meltings of Radioactive Materials*, Yusko, J.G., Pennsylvania Department of Environmental Protection (2004).

To preserve consumer confidence and the safe and continued operation of their mills, metals recycling companies have implemented the use of sophisticated radiological detection devices to screen scrap shipments before they enter a facility. Many facilities also retest their scrap feedstock before it enters the furnace. However, even the most advanced detection systems cannot be 100 percent effective in locating a single shielded source within a truckload or rail car of scrap. Moreover, if the shield on the source remains fully intact throughout the scrapping process, the source may not be detectable at all.

In order to screen the incoming scrap most effectively, metals recycling companies calibrate their detection equipment to be as sensitive as possible; oftentimes at, or slightly, above, background levels. Consequently, low-level sources, with activity levels that may not pose exposure concerns, will trip the sensors on a regular basis. A conservative estimate, based on conversations with MIRC member companies, indicates that a typical mill may sound between 20-50 false positives – *per month.* Each of these requires a response. To avoid such a large number of disruptions, MIRC's concern is that mills may be forced to decrease the sensitivity of their equipment so that the number of false positive alerts becomes more manageable. However, in "turning up the dial" on their radiation detection equipment, mills are exposed to a greater risk of melting a high-level source. The more sources that are unaccounted for, the greater this risk.

III. Issues Concerning the Proposed Rule

The rule proposed in July, 2005 would substantially assist the metals recycling industry in eliminating radioactive sources from its feedstock because it provides better oversight, management and stewardship of certain sealed sources. However, NRC's failure to include Category 3 sealed sources in the NSTS means that the proposed rule will not adequately protect the public health and safety.

Category 3 sealed sources are among the most numerous and dangerous categories of sealed sources in commerce today. Category 3 sources are the most likely to be lost, stolen, or improperly disposed of, and, therefore, the most likely to cause dangerous exposures to metals recycling employees and the general public. Thus, they should be covered by the tracking program.

MIRC is not alone in calling for NRC to expand the NSTS to include Category 3 sources. The International Atomic Energy Agency ("IAEA") specifically recommended that every country implement a national strategy to track the "status of *at least all Category 1, 2, and 3 sources.*"[5] Similarly, the U.S. Government Accountability Office issued a report detailing the potentially dangerous inability of NRC to track sealed sources and recommended that NRC

[5] *Strengthening Control Over Radioactive sources, in Authorized Use and Regaining Control Over Orphaned Sources: National Strategies,* IAEA-TECDOC-1388 (Vienna, Austria: February 2004) *(emphasis added).*

expand the NSTS proposal to include Category 3 sealed sources.[6] Additionally, during the comment period for the July 2005 proposed rule, the Health Physics Society, a noted independent scientific organization of professionals in radiation safety, informed NRC that the NSTS would fall short of its goals by not including Category 3 sources.

Most recently, the NRC's own Office of the Inspector General ("OIG") published the results of its Audit on the Development of the National Source Tracking System ("Audit Report").[7] Using NRC's own guidelines, the OIG determined that, as proposed, the NSTS is inadequate because "it will not include source tracking thresholds beyond the minimum requirement set for the IAEA's Code of Conduct."[8] Among the shortcomings highlighted in the audit report was the NRC's failure to include Category 3 sources in the NSTS. The OIG recommended that NRC amend its proposed rule and conduct a regulatory analysis to "include an assessment of expanding materials tracked in NSTS to contain Categories 3, 4, and 5."[9] We have enclosed this Audit Report for your review.

IV. Recommendations

We find it extremely disappointing that, faced with the criticism of the international community, the Federal government watchdog, NRC's own Office of the Inspector General, and knowledgeable stakeholders, including recognized radiation safety scientists and experts, NRC is shifting the statutory authority under which the rule will be promulgated but leaving its scope unchanged. Indeed, excluding Category 3 sources from coverage is even more puzzling now, when the rule is to be based on NRC's authority to protect public health and safety, then it was when national security concerns were cited as the basis for the proposed rule.

As we have stated numerous times, MIRC supports the concept of the NSTS. Assignment of unique serial numbers is critical to ensure that sources are properly managed throughout their use and at the end of their useful lives. Requiring licensees to assess their inventory on an annual basis is also necessary to ensure that proper stewardship is taking place. Requiring prompt and accurate reporting of all sealed source transactions gives NRC information the necessary to ensure that sources are monitored and never improperly disposed. However, from the perspective of public health and safety, these common sense steps are equally necessary to track Category 3 sources, especially those sources that contain radioactivity levels that are nearly comparable to Category 2 sources.

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[6] *Nuclear Security: DOE Needs Better Information to Guide its Expanded Recovery of Sealed Radiological Sources.* GAO-03-483 (Sept. 2005).

[7] *Audit of the Development of the National Source Tracking System,* OIG-06-A-10 (Feb. 23, 2006) (enclosed).

[8] *Id.* at 8.

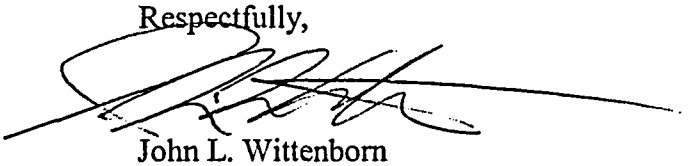
[9] *Id.* at 16.

Category 3 sealed sources pose a clear and present danger to the metals recycling industry, its employees and the surrounding community. Without adequate tracking and monitoring, the number and gravity of inadvertent melts will continue to rise.

MIRC does not object to NRC's proposal to change the basis of the rule so as to focus on protection of public health and safety. However, we respectfully request that NRC *actually* make the proposed rule more protective of public health and safety by including Category 3 sources in the NSTS.

Thank you for the opportunity to comment on this important rulemaking. If you have any questions, please feel free to contact John Wittenborn at 202.342.8514 or jwittenborn@kelleydrye.com.

Respectfully,



John L. Wittenborn
KELLEY DRYE & WARREN, LLP
3050 K Street, N.W.
Suite 400
Washington, DC 20007
Counsel to the Metals Industry Recycling Coalition

Enclosure

AUDIT REPORT

Audit of the Development of the
National Source Tracking System

OIG-06-A-10 February 23, 2006

All publicly available OIG reports (including this report) are accessible through NRC's Web site at:
http:/www.nrc.gov/reading-rm/doc-collections/insp-gen/

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

February 23, 2006

OFFICE OF THE
INSPECTOR GENERAL

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Stephen D. Dingbaum
Assistant Inspector General for Audits

SUBJECT: AUDIT OF THE DEVELOPMENT OF THE NATIONAL SOURCE TRACKING SYSTEM (OIG-06-A-10)

This report presents the results of the subject audit. Agency comments provided at the exit conference on December 6, 2005, and the agency's written response, dated February 1, 2006, have been incorporated, as appropriate, into this report. Appendix B contains the agency's written comments and Appendix C contains OIG's responses.

Please provide information on actions taken or planned on each of the recommendations within 30 days of the date of this memorandum. Actions taken or planned are subject to OIG follow-up as stated in Management Directive 6.1.

We appreciate the courtesies and cooperation extended to us by members of your staff during the audit. If you have any questions or comments about our report, please feel free to contact me on 301-415-5915 or Anthony Lipuma on 301-415-5910.

Attachment: As stated

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EXECUTIVE SUMMARY

BACKGROUND

The U.S. Nuclear Regulatory Commission's (NRC) mandate to protect public health and safety and the environment, and to provide for the common defense and security, includes regulation of medical, academic, and industrial uses of radioactive material generated by or from a nuclear reactor. NRC regulations define this radioactive material as byproduct material.[1] Examples of byproduct material include substances containing radioactive isotopes such as cobalt-60, cesium-137, and iridium-192.

In accordance with section 274 of the Atomic Energy Act, NRC relinquished its authority to regulate certain byproduct material to 33 States. The 33 States, which have entered into an agreement assuming regulatory authority from NRC, are called Agreement States.

NRC administers about 4,500 material licenses and the Agreement States administer about 17,300 materials licenses for a total of about 21,800 licenses. Each year, the agency issues approximately 4,200 new licenses, license renewals, and license amendments for nuclear materials licenses.

There is widespread use of byproduct material in the United States and abroad for peaceful purposes. However, the events of September 11, 2001, heightened the nation's concerns that the loss or theft of radioactive material could lead to malicious use.

The International Atomic Energy Agency (IAEA) realized the need for a categorization system for radioactive materials. As a result, IAEA developed a categorization system that provides a relative ranking and grouping of sources and practices on which regulatory decisions can be based. In January 2004, the IAEA published the Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) that is the current standard the international community uses to govern the safety and security of radioactive material based on the categorization system.

[1] Byproduct material excludes uranium or transuranic isotopes which the NRC regulates as either source materials or special nuclear material.

PURPOSE

The overall purpose of this audit was to determine whether NRC's oversight of byproduct and sealed source materials provides reasonable assurance that licensees are using the materials safely and account for and control the materials. Because NRC is planning to use the proposed *National Source Tracking System* (NSTS), an agency database to track all phases of the life cycle of byproduct material, our audit focused on the development of the NSTS.

RESULTS IN BRIEF

NRC's regulatory analysis guidance provides the framework for making regulatory decisions. This framework includes basing decisions on adequate information and identifying and evaluating alternative approaches in the regulatory analysis. As proposed, the NSTS may be inadequate because the supportive regulatory analysis is based on unreliable data and does not consider viable options as stated by the IAEA's Code of Conduct. As a result, NRC's proposed tracking system, NSTS, may not account for all byproduct material that represents a risk to the common defense and security and public health and safety. Such risks could result in economic, psychological, and physical harm to the United States and public.

RECOMMENDATIONS

This report makes two recommendations to the Executive Director for Operations: 1) to conduct a comprehensive regulatory analysis for the NSTS that explores other viable options and 2) to validate the existing data in the Interim Database.

AGENCY COMMENTS

On February 1, 2006, the Deputy Executive Director for Materials, Research, State, and Compliance Programs provided comments concerning the draft audit report. Appendix B contains NRC's formal comments and Appendix C contains OIG's specific response to each comment.

ABBREVIATIONS AND ACRONYMS

CAIB	Columbia Accident Investigation Board
Code of Conduct	Code of Conduct on the Safety and Security of Radioactive Sources
DOE	Department of Energy
GAO	Government Accountability Office
IAEA	International Atomic Energy Agency
NRC	Nuclear Regulatory Commission
NSTS	National Source Tracking System
OIG	Office of the Inspector General
RDD	radiological dispersal device

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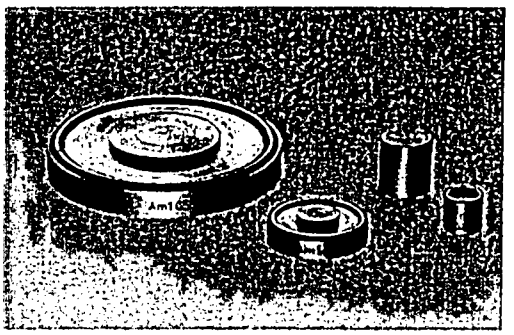
I. BACKGROUND

The U.S. Nuclear Regulatory Commission's (NRC) mandate to protect public health and safety and the environment, and to provide for the common defense and security, includes regulation of medical, academic, and industrial uses of radioactive material generated by or from a nuclear reactor. NRC regulations define this radioactive material as byproduct material.[2] Examples of byproduct material include substances containing radioactive isotopes such as cobalt-60, cesium-137, and iridium-192.

The term *radioactive material* describes any material emitting radiation. Radioactive material may be in the form of a *sealed source*, which is the term used to describe radioactive material that is permanently sealed in a capsule or closely bonded in a solid form. The term *radioactive source* is also used to describe a sealed source. Additionally, *bulk material* is radioactive material that can easily be subdivided into smaller quantities.



Industrial Sealed Sources
Source: Department of Energy

The degree of potency of radioactive material is the *activity level.* Activity level is most commonly measured in the United States by the curie.[3] Because material can have different activity levels per unit weight or volume, the physical size of radioactive material does not indicate the potential health risk. Some radioactive material is found in nature, such as radium,[4] but most radioactive material is produced artificially in nuclear reactors or particle accelerators. The term *byproduct material* describes the subset of radioactive material that is artificially produced.

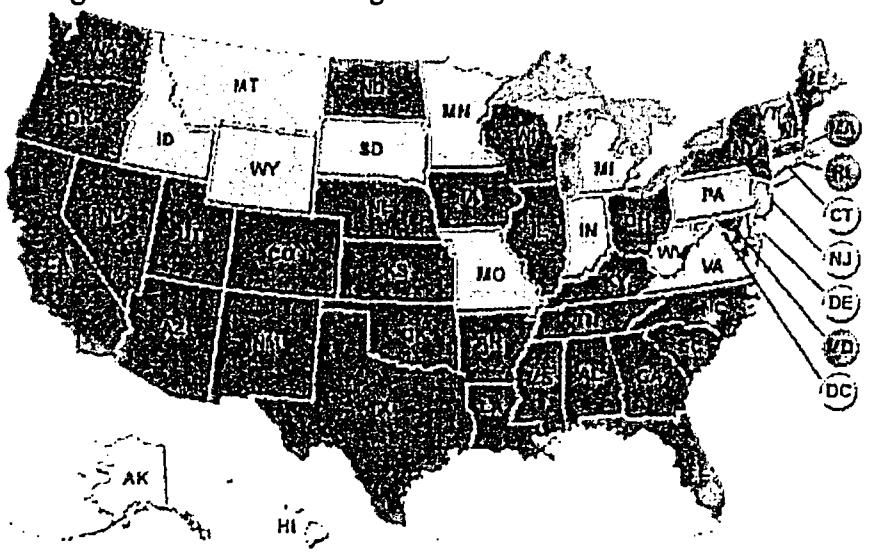
[2] Byproduct material excludes uranium or transuranic isotopes which the NRC regulates as either source materials or special nuclear material.
[3] A curie is the traditional unit of activity. It is the measurement of the rate of decay, or transformation, of a radionuclide.
[4] The Atomic Energy Act was amended in August 2005 to add any discrete source of radium-226 to NRC's jurisdiction of byproduct material.

Agreement States

In accordance with section 274 of the Atomic Energy Act, NRC relinquished its authority to regulate certain byproduct material to 33 States. The States must first demonstrate that their regulatory programs are compatible with NRC's program and adequate to protect public health and safety. The 33 States, which have entered into an agreement assuming this regulatory authority from NRC, are called Agreement States.

Figure 1

Agreement and Non-Agreement States



Agreement States Non-Agreement States Letter of Intent-AS

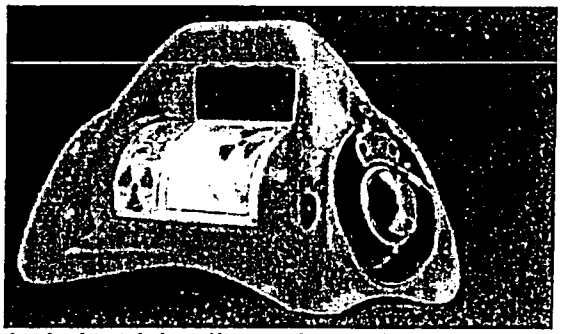
Source: www.hsrd.ornl.gov/nrc/home.html [as of February 2006]

NRC administers about 4,500 material licenses and the Agreement States administer about 17,300 materials licenses for a total of about 21,800 licenses. Each year, the agency issues approximately 4,200 new licenses, license renewals, and license amendments for nuclear materials licenses.[5]

[5] Information Digest. 2005-2006 Edition. NUREG-1350, Volume 17. U.S. Nuclear Regulatory Commission, July 2005.

Uses of Byproduct Material

There is widespread use of byproduct material in the United States and abroad for peaceful purposes. Commercial licensees use byproduct material in areas such as industrial radiography, manufacture of gauging devices, gas chromatography, and well logging. Byproduct material is also used by the general public in various consumer products, such as smoke detectors, "Exit" signs, static eliminators, and luminous watch dials. Medical licensees use byproduct material for the diagnosis or treatment of patients in hospitals or physicians' offices, with an estimated 10 to 12 million clinical procedures performed annually. Colleges, universities, and other academic institutions use byproduct material in course work and research.



An industrial radiography device
Source: Department of Energy

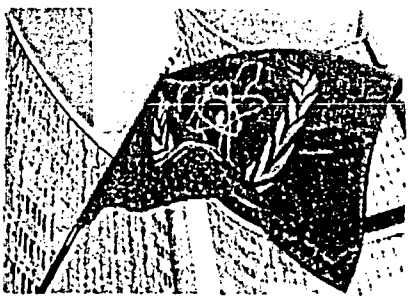
Aftermath of 9/11

The events of September 11, 2001, heightened the nation's concerns that the loss or theft of radioactive material could lead to malicious use in a radiological dispersal device (RDD). An RDD, also known as a dirty bomb, is a conventional explosive that incorporates radioactive material and releases it on detonation. The major purpose for an RDD is to create terror and disruption, not to cause death by radiation.

In July 2002, the Department of Energy (DOE) and NRC established an Interagency Working Group on RDDs to cooperate on areas where immediate progress towards the control of radioactive material could be achieved. One area that the group examined was options for establishing a national source tracking system because NRC's regulations do not require licensees to report radioactive material inventories to NRC. The DOE/NRC Working Group recommended that NRC develop a tracking system to better understand and monitor the location and movement of certain radioactive sources.

IAEA Categorization System

The International Atomic Energy Agency (IAEA)[6] realized that it needed a categorization system for radioactive materials. In July 2003, IAEA issued a technical document[7] on the Categorization of Radioactive Sources. The purpose of IAEA's technical document was to provide a fundamental and internationally harmonized basis for risk-informed decision making. IAEA noted that *high activity sources*,[8] "if not managed safely or securely, can cause severe deterministic effects[9] to individuals in a short period of time, whereas low activity sources are unlikely to cause such effects." As a result, IAEA developed a categorization system that provides a relative ranking and grouping of sources and practices on which regulatory decisions can be based. In January 2004, the IAEA published the Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) that is the current standard the international community uses to govern the safety and security of radioactive material based on the categorization system.



IAEA Flag
Source: www.iaea.org

[6] The IAEA is part of the United Nations and is recognized as the world's center of nuclear cooperation and works for the safe, secure, and peaceful use of nuclear technologies.
[7] IAEA TECDOC-1344, *Categorization of Radiation Sources*, July 2003.
[8] The term *high activity sources* refers to the radioactive material in a range of radionuclides, forms, and quantities that needs to be considered in IAEA's categorization system.
[9] A deterministic effect is fatal or life threatening or results in a permanent injury that decreases the quality of life.

II. PURPOSE

The overall purpose of this audit was to determine whether NRC's oversight of byproduct and sealed source materials provides reasonable assurance that licensees are using the materials safely and account for and control the materials. Because NRC is planning to use the proposed *National Source Tracking System* (NSTS), an agency database to track all phases of the life cycle of byproduct material, our audit focused on the development of the NSTS.

III. FINDING

As Proposed, the NSTS May be Inadequate

NRC's regulatory analysis guidance provides the framework for making regulatory decisions. This framework includes basing decisions on adequate information and identifying and evaluating alternative approaches in the regulatory analysis. As proposed, the NSTS may be inadequate because the supportive regulatory analysis is based on unreliable data and does not consider viable options as stated by the IAEA's Code of Conduct. As a result, NRC may not account for all byproduct material that represents a risk to the common defense and security and public health and safety. Such risks could result in economic, psychological, and physical harm to the United States and public.

Regulatory Analysis Guidance

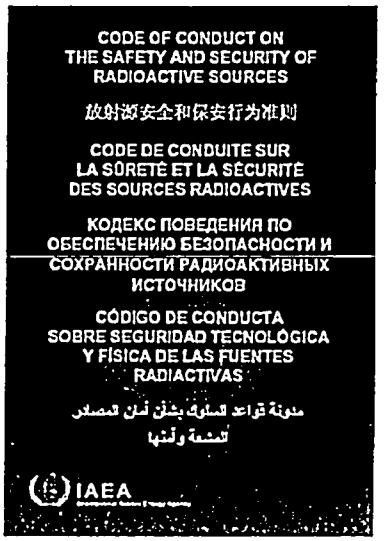
A regulatory analysis[10] is a structured evaluation of all relevant factors associated with making a regulatory decision. To ensure that NRC's regulatory decisions support its statutory responsibilities and are based on adequate information, NRC issued *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission.*[11] NRC also issued the *Regulatory Analysis Technical Evaluation Handbook*[12] to implement the policies in its guidelines.

Identifying and evaluating alternative approaches is a key element in meeting the letter and spirit of NRC's regulatory analysis policy. A broad and comprehensive list of alternatives should be developed, and a preliminary analysis of the feasibility, values, and impacts of each alternative should be performed. Some alternatives may be eliminated for a variety of reasons. However, the regulatory analysis document should list all alternatives identified and considered, and provide a brief explanation of the reasons for eliminating certain alternatives during the preliminary analysis. IAEA's Code of Conduct provides a basis and alternatives for controlling radioactive sources.

[10] NRC does not have a statutory mandate to conduct regulatory analyses; however, it voluntarily began performing them in 1976.
[11] NUREG/BR-0058, Revision 4, September 2004.
[12] NUREG/BR-0184, January 1997.

IAEA Code of Conduct

The Code of Conduct applies to all radioactive sources that may pose a significant risk to individuals, society, and the environment. It provides guidance to minimize the likelihood of loss of control of radioactive sources and to provide measures to reduce the possibility of malicious acts. Through the Code of Conduct, IAEA's overall strategy is to assist Member States[13] to create and strengthen national regulatory infrastructures to ensure that significant radioactive sources are localized, registered, secured, and controlled from "cradle to grave."



Source: www.iaea.org

The objectives of the Code of Conduct are to -

1. achieve and maintain a high level of safety and security of radioactive sources, and

2. prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources.

To help meet these objectives, the IAEA recommends in the Code of Conduct that every Member State establish a national register of radioactive sources. While the IAEA classifies sources into 5 categories, it notes that sources in categories 1 through 3 are designated as varying degrees of dangerous. IAEA defines a dangerous source as: "A source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects." [See Figure 2 for details.]

[13] The IAEA refers to its member countries as States. The United States is an IAEA member.

Figure 2

Categorization of Radioactive Sources

Category	Relative Radiation Hazard
1	Personally Extremely Dangerous
2	Personally Very Dangerous
3	Personally Dangerous
4	Unlikely to be Dangerous
5	Not Dangerous

Source: IAEA-TECDOC-1344

The Code of Conduct states that, *as a minimum* (emphasis added), national registers should include categories 1 and 2 radioactive sources. Further, countries should devote appropriate attention to the regulation of other potentially harmful radioactive sources. While the Code of Conduct does not specifically state that bulk material should be tracked, it does state that there may be circumstances where such material should be managed in accordance with the objectives of the Code of Conduct.

To highlight the options implied in the Code of Conduct, the IAEA recognized France's nuclear material program for having implemented a system for controlling radioactive material that could be used as a model for other countries. The French system of radioactive material oversight is a life cycle approach which includes tracking radioactive material from manufacture until disposal. The French system tracks Code of Conduct categories 1 through 5 radioactive sources and includes bulk materials.

With respect to source tracking, the French system requires that each transfer or acquisition be reported to its computerized database. Through this system, France intends to oversee source transfers, create a national inventory, and track the inventory and movement of sources in Code of Conduct categories 1 through 5.

As Proposed, the NSTS May Be Inadequate

NRC is proposing to build the NSTS, a web-based system that will contain cradle-to-grave information on high-risk sealed sources. NRC's qualitative values for the NSTS include –

- improve security for nationally tracked sources,
- improve the understanding of the location of nationally tracked sources,
- improve regulatory efficiency,

- enhance NRC's ability to promote and maintain the common defense and security, and
- increase public confidence.

While the proposed NSTS would greatly improve NRC's data on licensed radioactive material, it may be inadequate. Under its current regulations, NRC's licensees are to provide data to the agency only on the types and quantities of nuclear material that they are *licensed to possess* – not what they actually have in inventory. Furthermore, NRC does not maintain actual information on Agreement State licensees – that is the responsibility of each of the 33 Agreement States. To address this situation, NRC is proposing to amend its regulations to implement the NSTS. Under this amendment, NRC and Agreement State licensees will be required to report information on the manufacture, transfer, receipt, and disposal of sealed sources at or above the Code of Conduct Category 2 threshold. Because NRC's proposed NSTS will include transaction tracking features, it will be more than a national register. However, as proposed the NSTS will not include source tracking thresholds beyond the minimum requirement set forth in the IAEA's Code of Conduct.

In a recent report,[14] the Government Accountability Office (GAO) found that, as proposed, NSTS (a national registry) would be of little use to DOE in its efforts for the recovery and disposal of unwanted sealed radiological sources. GAO reported that as presently designed, NSTS will only track individual sources with high radioactivity concentrations and will not include essentially all of the sources of lesser radioactivity that DOE has recovered. The GAO report also stated that the combined activity posed from the individual sources poses enough of a safety and security risk to warrant their recovery by DOE – but the sources will not be tracked in NSTS.

In September 2005, the Health Physics Society[15] sent a letter to NRC stating its belief that the NSTS should result in enhanced public health and safety as well as national security. However, the Society believes that the proposed NSTS will fall short of this goal because it will only track Code of Conduct sources at or above Category 2 and will not include Category 3 sources which IAEA terms as being *dangerous*.

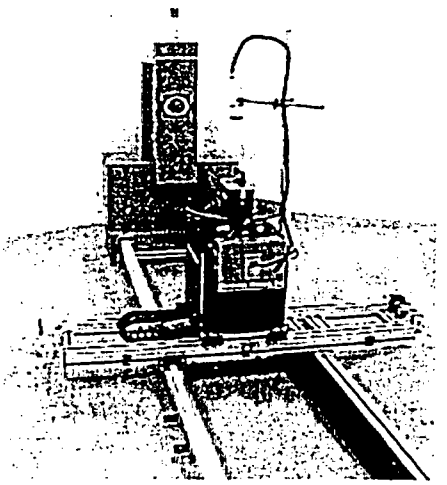
[14] Nuclear Security: DOE Needs Better Information to Guide Its Expanded Recovery of Sealed Radiological Sources. GAO-05-967, September 2005.
[15] The Health Physics Society is an independent scientific organization of professionals in radiation safety.

Data Used for the Regulatory Analysis is Unreliable

Because NRC did not have information regarding the sources and quantities possessed by licensees, the Commission directed NRC staff to collect data on a one-time basis. In November 2003, NRC requested licensees to report any single source equal to or larger than Code of Conduct Category 2 values. Licensees were also asked to report the aggregation[16] of multiple co-located sources that equaled or exceeded Category 2 values. In its instructions to licensees, NRC defined co-location as sources that can be accessed by breaching a single security barrier (e.g., a locked door at the entrance to a storage room). Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room).

The Commission decided that until the NSTS is implemented, NRC will maintain an interim inventory of sources at or above Code of Conduct Category 2 values that will be updated annually. As a result, NRC established the Interim Database and in January 2005, the agency again began querying all licensees authorized to possess these sources. NRC instructed licensees that future rounds will be similar, but will not include aggregation of co-located sources.

In developing the NSTS regulatory analysis, NRC staff based their review on the first round of data collected in the Interim Database and their best judgment. The Interim Database contained information on about 3,600 Category 1 and/or 2 sources.[17] Yet, staff estimated that licensees possess approximately 75,000 Category 1 and/or 2 sources. Staff members believe that a large part of the difference between the number of sources in the Interim Database and their estimate is attributed to the way irradiators and gamma knifes were counted in the Interim Database. That is, these devices were treated as single sources in the Interim Database, when actually the devices could each contain from a few to over 1,500 individual sources. An NRC staff member said that



Gamma Beam Irradiator
Source: Hopewell Designs, Inc.

[16] Aggregation is two or more sources that are in close proximity and their total activity is at or above a specified Code of Conduct category threshold.

[17] *Regulatory Analysis for the Proposed Rule on National Source Tracking of Sealed Sources – 10 CFR Parts 20, 32, and 150*; Draft Report; April 28, 2005; page 7, section 3.2.2.2

overall the data in the Interim Database is probably accurate within a factor of 10. A *factor of ten* means that the data could be off by a multiple of ten. For example, if the database indicated 3,600 sources, one could reasonably expect that the actual number of sources would be between 360 and 36,000. Therefore, NRC cannot reasonably estimate the number of radioactive sources in the United States for each of the Code of Conduct categories.

Viable Options Not Considered

NRC staff conducted a regulatory analysis to evaluate the values and impacts associated with two regulatory options to address the tracking of radioactive material. Option 1 was to take no action. Option 2 was to develop the NSTS including the inventory of Code of Conduct Category 1 and/or 2 of nationally tracked sealed sources. As of the date of this audit report, the regulatory analysis for the NSTS that is publicly available is labeled as a *draft* document and is dated April 28, 2005.

In August 2003, before developing its regulatory analysis, NRC had already committed to Congress that it would develop a requirement for tracking Code of Conduct sources. As a result, Option 1 (no action) of the regulatory analysis really was not an alternative. Therefore, in reality, NRC staff provided agency decision-makers with only one option – develop NSTS to track sealed sources at or above the Category 2 threshold. Staff did not provide decision-makers with other options such as tracking radioactive material beyond Category 2, including the aggregation of co-located sources, or tracking bulk material. Furthermore, a consideration regarding the acquisition of sources by a malevolent party was not documented in the regulatory analysis.

Tracking Beyond Category 2

The regulatory analysis does not offer options implied in the Code of Conduct such as tracking radioactive material to categories lower than the Category 2 threshold. Agency managers and staff were unable to provide the number of sources in the United States for each category. One NRC official offered that there are many Code of Conduct Category 3 sources, and another manager said that if Category 3 sources were included in NSTS, the numbers would be "significantly expanded." Yet, another staff member opined that some people are overestimating the number of Category 3 sources.

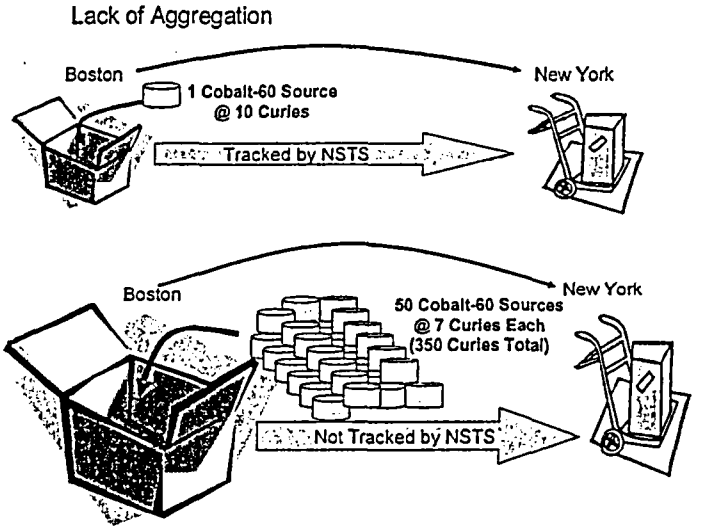
NRC staff did not conduct a formal analysis to determine the number of sources or feasibility of tracking radioactive material beyond Category 2.

Including Source Aggregation and Bulk Material

The Code of Conduct states that in addition to the categorization of sources, appropriate attention should be given to the aggregation of lower activity sources. Yet, the regulatory analysis does not consider tracking sources that are in a single storage or use location where the sources are in close proximity and their total activity is at or above a specified Code of Conduct category threshold. This practice is known as aggregation.

Figure 3 provides an example of a fundamental problem that can occur when aggregation is not considered in a transaction involving radioactive material. Cobalt-60 is used in this example. Per the Code of Conduct, the Category 2 reporting threshold for Cobalt-60 is 8 curies. Therefore, a transaction involving *one* Cobalt-60 source at 10 curies would be tracked in the NSTS because the single source is greater than the Category 2 threshold. However, a transaction involving *fifty* Cobalt-60 sources at 7 curies each would not be tracked in the NSTS because the 7-curie individual sources fall below the Category 2 threshold - - not withstanding the fact that the total activity of sources in this transaction is 350 curies.

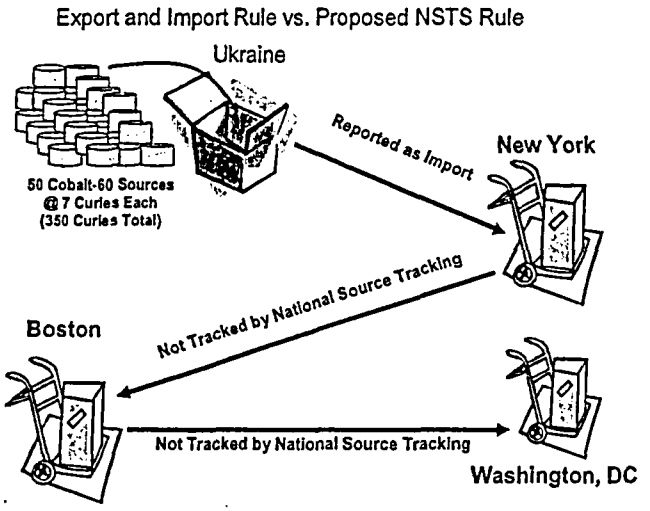
Figure 3



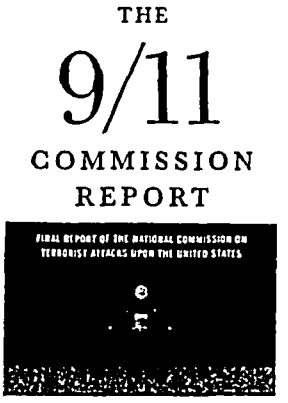
Additionally, NRC recently developed its Export and Import Rule, which takes into consideration radioactive material associated with Code of Conduct categories 1 and 2. The new rule goes beyond the Code of Conduct recommendation to track sealed sources and includes the export and import of bulk material. Further, this newly developed rule requires that licensees report to NRC when they export or import radioactive material of concern that aggregates to or above the Category 2 threshold. Figure 4 provides an example of what can occur when aggregation is not considered in domestic tracking. Cobalt-60 is used in the example. NRC's reporting

threshold for Category 2 (based on the Code of Conduct Category 2 threshold) is 8 curies. Therefore, in accordance with NRC's Export and Import Rule, a transaction involving *ten* Cobalt-60 sources at 7 curies each would be tracked to the United States border. However, once the Cobalt-60 sources are in the United States, the sources would no longer be tracked, because the *ten* 7-curie individual sources fall below the Category 2 threshold. NRC's proposed NSTS rule, which does not include the tracking of bulk material or aggregation, is not consistent with its Export and Import Rule.

Figure 4



Malevolent Uses Not Considered



Source: www.9-11 commission.gov/

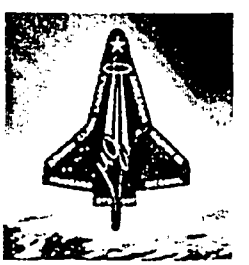
When developing tracking options (e.g., tracking beyond Category 2, aggregation, bulk material), a consideration that should be included in the regulatory analysis is the acquisition of sources by a malevolent party through a series of apparently routine byproduct transactions. Traditionally, security requirements for radioactive sources were focused on petty theft or accidental access to radioactive materials. However, due to the September 11, 2001, terrorist attacks, a new range of security threats emerged. One such example is the diversion of radioactive materials from legal to illegal and criminal uses - such as terrorist violence. The *9/11 Commission Report*[18] noted the threat of a

[18] The President of the United States and Congress created the National Commission on Terrorists Attacks (9/11 Commission). That Commission produced the authoritative review of the attacks of September 11, 2001, and published their final report public report on July 22, 2004.

terrorist cell – a small group composed of intelligent and dedicated individuals. Such a cell is patient and seeks to operate without detection by government or law enforcement officials. Given this profile, a terrorist cell may attempt to accumulate radioactive sources through normal commercial means for apparently legal purposes. In an effort to avoid detection, a cell may likely attempt to acquire sources below thresholds that require reports to Federal or state agencies. An NRC staff member stated a concern that a terrorist will "legally" acquire radioactive material.

NRC Not Considering Potential Risks

NRC used the regulatory analysis as a basis for its draft rule, *National Source Tracking of Sealed Sources.* Yet, the regulatory analysis was based on unreliable data from the Interim Database and did not provide NRC decision-makers with viable options relevant to the NSTS. An important lesson that directly applies to the NSTS regulatory analysis was learned by the National Aeronautics and Space Administration after the Columbia space shuttle accident. The Columbia Accident Investigation Board (CAIB) found that, "Organizations interested in safety must take steps to guarantee that all relevant information is presented to decision-makers."[19] The CAIB also noted that "The investigation uncovered a troubling pattern in which Shuttle Program management made erroneous assumptions about the robustness of a system based on prior success rather than on dependable engineering data and rigorous testing." The NSTS regulatory analysis did not bring all relevant information to light because it --



Source: www.nasa.gov

1. did not contain viable options and

2. was based on unreliable data.

As a result, NRC may not account for all byproduct material that represents a risk to the common defense and security and public health and safety. Such risks could result in economic, psychological, and physical harm to the United States and public.

The 9/11 attacks had a cascading effect on the United States economy and terrorists have recognized the potential of economic warfare. According to a recent *Business Week* article, if a dirty

[19] Columbia Accident Investigation Board, National Aeronautics and Space Administration and the Government Printing Office, Washington, DC, August 2003

bomb exploded outside the New York Stock Exchange, economists estimate the eventual economic losses to be $1 trillion. Moreover, the most significant risk of an attack with a radiological weapon somewhere in the world in the next 10 years is from a dirty bomb, according to the June 2005 results from a United States-sponsored survey conducted among experts. An American citizen with known al-Qaeda ties was arrested in Chicago's O'Hare International Airport in 2002 on suspicion of planning to build and detonate a dirty bomb in an American city. Law enforcement officials believe that the suspect was on a reconnaissance mission for a future dirty-bomb attack.

Radioactive material that is not managed and controlled appropriately is currently having a large economic impact on the metal recycling industry. For example, in the United States from 1982 to 2004 there were approximately 34 instances when scrap was melted containing radioactive material. The cost of decontamination, disposal, and shutdown losses reached $23 million in a single incident and average in the range of $8 to $10 million in steel mini-mills. The cost of radioactive melt at a large integrated steel mill is estimated to run as high as $100 million or more.

If a dirty bomb did not injure many people, it could certainly cause terror and psychological distress. A radiological weapon made with comparatively weak radioactive material would be easier to assemble than a device using powerful material, but still be disruptive by exploiting public fear of radiation and rousing a disproportional emergency response. In the wrong hands, even a relatively small amount of radioactive material can cause the kind of public fear the United States experienced when anthrax-laced mail was sent to the Federal Government and media offices.

When radioactive material is managed according to standards in a safe and secure manner, the radiation risks to workers and the public are minimized. However, if radioactive material is not managed appropriately, as in the case of accidents or malicious use, it can cause a range of deterministic health effects resulting in acute radiation sickness, permanent injury, or even death.

IV. SUMMARY AND CONCLUSION

The events of September 11, 2001, changed the world forever. It is obvious that we will never live in a risk-free society. However, in line with its safety and security mission, NRC has the responsibility to take appropriate, meaningful steps to mitigate the dangers associated with the uses of radioactive material.

Tracking radioactive material, more specifically byproduct material, will not absolutely ensure physical protection or verify independently where all such material is located and that it is safely secured. However, if the NSTS is not robust, it will not meet NRC's qualitative values for the system. Those values include improving security and control of nationally tracked sources, improving regulatory efficiency, enhancing the nation's common defense and security, and increasing public confidence.

The NSTS was born out of concerns about the effects of a dirty bomb, the threat of which became a cause for concern after the events of 9/11. Yet, NRC is making significant decisions about the scope of the NSTS using unreliable data and without considering all viable options.

Recommendations

OIG recommends that the Executive Director for Operations –

1. Before the NSTS rulemaking is finalized, conduct a comprehensive regulatory analysis for NSTS that explores other viable options, such as those in the Code of Conduct. The regulatory analysis should include an assessment of expanding materials tracked in NSTS to contain categories 3, 4, and 5; aggregation of sources; and bulk material.

2. Validate the existing data in the Interim Database to ensure that reliable information is used in the NSTS regulatory analysis.

V. AGENCY COMMENTS

At an exit conference on December 6, 2005, NRC provided informal, written comments on the draft audit report. OIG incorporated the suggestions as appropriate. On December 20, 2005, OIG audit staff met with agency officials and further discussed the report. On January 9, 2006, OIG issued a formal draft report and on February 1, 2006, NRC provided formal written comments. OIG incorporated those comments, as appropriate, into the final report.

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Appendix A

SCOPE AND METHODOLOGY

The overall purpose of this audit was to determine whether NRC's oversight of byproduct and sealed source material provides reasonable assurance that licensees are using the materials safely and account for and control the materials. Because the objective covers such a broad scope, we narrowed our review and the focus of this report to determine if the National Source Tracking System (NSTS) will provide an effective oversight means to track all phases of the life cycle of byproduct material.

In order to fulfill its objective, the OIG audit team reviewed and analyzed relevant legislation, such as the Atomic Energy Act and the Energy Policy Act of 2005. The audit team also reviewed and analyzed International Atomic Energy Agency guidance – expressly its technical reports and the Code of Conduct.

The OIG audit team reviewed and analyzed documented materials including NRC guidance, speeches, and reports. Specifically, the audit team analyzed and compared *NRC's Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission* and the associated Handbook to the regulatory analysis that NRC staff prepared for the proposed National Source Tracking System. The audit team also focused on data in the agency's Interim Database and monitored current events associated with byproduct material.

The OIG audit team interviewed NRC managers and staff, as well people external to NRC. The team met with officials from various NRC offices such as the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Security and Incident Response, and the Office of the General Counsel. Also, the audit team met with officials from the Department of Energy, the National Nuclear Security Administration, and the State Department. Further, the audit team met with an official from the French Atomic Energy Commission, Embassy of France.

This audit was conducted in accordance with generally accepted Government auditing standards and included a review of management controls related to the objective of this audit. This audit was conducted from February 2005 to September 2005.

Major contributors to this report are Anthony Lipuma, Team Leader; Sherri Miotla, Audit Manager; Michael Cash, Technical Advisor; Debra Lipkey, Senior Management Analyst; and R. K. Wild, Senior Management Analyst.

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Appendix B

AGENCY FORMAL COMMENTS

From: Melinda Malloy
To: ACL@nrc.gov
Date: 2/15/06 4:09PM
Subject: OUO markings on comment memo re: draft NSTS audit report

Tony,

The staff provided written comments on OIG's final draft audit report on NRC's development of the National Source Tracking System in a memo from Martin Virgilio, DEDMRS to Steve Dingbaum dated February 1, 2006 (available at ML060170199). This document was marked "Official Use Only - Sensitive Internal Information" due to the markings on the draft audit report. OEDO and NMSS have reviewed this document and have no objection to its inclusion in OIG's final audit report. To facilitate completion of the audit report, you may strike out the markings, top & bottom, on all pages of the memo and annotate the first page to reflect our agreement to put the memo in the final audit report. As the memo has already been declared as an official record, I will work with ADAMS IM to correct the copy of the official record in ADAMS. If they tell me to do this another way, I'll let you know as soon as possible.

Melinda Malloy, OEDO
OIG Audit Liaison
415-1785

CC: CAM4@nrc.gov,PFG@nrc.gov,PKH@nrc.gov,CGM@nrc.gov

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

February 1, 2006

MEMORANDUM TO: Stephen D. Dingbaum
Assistant Inspector General for Audits
Office of the Inspector General

FROM: Martin J. Virgilio
Deputy Executive Director for Materials, Research,
State and Compliance Programs
Office of the Executive Director for Operations

SUBJECT: DRAFT REPORT: AUDIT OF THE DEVELOPMENT OF THE NATIONAL SOURCE TRACKING SYSTEM

In response to your memorandum dated January 9, 2006, the U.S. Nuclear Regulatory Commission staff has the enclosed comments on the draft report. If you have questions, please contact Patricia Holahan at (301) 415-8125.

Enclosure:
Comments on Office of the Inspector General
Draft Report

Official Use Only Marking Removed
Per OEDO Email Dated 02/15/06

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COMMENTS ON OFFICE OF INSPECTOR GENERAL DRAFT REPORT:
AUDIT OF THE DEVELOPMENT OF THE NATIONAL SOURCE TRACKING SYSTEM

General Comments

1. The Office of the Inspector General (OIG) notes that "The overall purpose of this audit was to determine whether NRC's oversight of byproduct and sealed source materials provides reasonable assurance that licensees are using the materials safely and account for and control the materials." The OIG and staff agree that the National Source Tracking System (NSTS) is one of many elements of the overall program to ensure that appropriate controls are implemented around the use of radioactive materials . With respect to Category 3 sources, the existing regulatory controls include the comprehensive health and safety and environmental measures of licensing, inspection, and reporting. As many as half of Category 3 sources are individually tracked in the General License Tracking System and the remaining Category 3 sources are specifically licensed. All Category 3 sources held by the DOE meet DOE's "accountable sealed radioactive source" criteria and therefore are inventoried and are subject to added reporting requirements.

NRC has issued orders for additional security measures to certain materials licensees with quantities of radionuclides of security concern. The orders took into account aggregation and co-location of material. These measures, rather than the NSTS, are directly concerned with the protection of material to preclude its use in the kind of RDD scenarios suggested on pp. 18 and 19 of the draft OIG report.

2. The decision of whether or not to include Category 3 sources in the upcoming rulemaking is pending before the Commission and continues to be addressed by the staff and by the Radiation Source Protection and Security Task Force established by the Energy Policy Act. While the Regulatory Analysis does not include a thorough examination of the costs and benefits of including Category 3 sources, the issue has previously been addressed by the staff, the Working Groups, the Interagency Coordination Committee, and the Steering Committee for NSTS, and it is discussed at length in the Federal Register Notice for the proposed rule.

The Commission has reviewed the NSTS rule and the planned system and approved publication of the proposed rule (70 FR 43646, July 28, 2005). There continues to be discussion of whether and how to include Category 3 sources. That remains an open question for the future but to include them now would greatly delay deployment of the system, possibly diminishing health, safety, and security and failing to fulfill the Nuclear Regulatory Commission's (NRC) commitments to Congress, other Federal and State agencies, and the International Atomic Energy Agency (IAEA). The staff is planning to send the Commission a paper concerning sources below Category 2, including generally licensed sources, in March. The NSTS has been designed so that its basic architecture will accommodate Category 3 sources if the decision is made to eventually include them.

3. Staff is now assessing the comments on the pending rulemaking. In parallel, staff is examining a range of options for improving the overall program to ensure appropriate controls for sources below Category 2. These options include specifically licensing all Category 3 sources by placing activity limits on general licenses, creating an inventory requirement for all

Enclosure

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Category 3 and above sources, and requiring source tracking for some sources below Category 2. The staff will weigh the costs and benefits of any proposed action and any option that includes rulemaking will include a regulatory analysis.

4. The Energy Policy Act of 2005, in Section 170H, establishes an Interagency Task Force on Radiation Source Protection and Security, chaired by Chairman Diaz, and directs it to report to Congress and the President on recommendations for, among other matters,

- "modifications to the national tracking system for radiation sources;"
- "the establishment of, or modifications to, a national system (including user fees and other methods) to provide for the proper disposal of radiation sources secured under this Act;"

The Task Force, including most of the same agencies that were involved in the development of the NSTS, will be dealing with concerns on the NSTS at a high level and can be expected to make recommendations that resolve policy questions such as those raised in the OIG report.

5. SRM-SECY-05-0201, "Implementation Of the Energy Policy Act of 2005" requires the staff to again consider including Category 3 sources in the NSTS:

> "6. Section 651(d)(1) Radiation Source Protection, National Academy of Sciences Study - This section in the Energy Policy Act contains the definition of 'Radiation Source,' part B of which states 'any other material that poses a threat such that the material is subject to this section, as determined by the Commission, by regulation....' The staff has asked for comments on the inclusion of Category 3 sources, or an appropriate subset of Category 3 sources, in the National Source Tracking System (NSTS) and the staff should carefully consider those comments. If, ultimately, Category 3 sources are not included in the NSTS rule, the staff should consider doing so in a separate rulemaking and either develop a schedule and cost for this rulemaking or document in some manner that a separate rulemaking is not needed and the rationale for this statement."

6. The identification of materials of hazard in the Department of Energy (DOE)/NRC Joint Report on "Radiological Dispersal Devices" (RDDs) was intended to guide assessments regarding a system to track sources. The results can be used to define the NSTS population and future tracking priorities.

The NRC action threshold defined in the DOE/NRC RDD report included consideration of respirable and release fractions. This threshold roughly equates to the IAEA Category II definition.

Specific Comments

1. p. 10, lines 23-26; p. 11, lines 1-4 - With reference to the citation of the U.S. Government Accountability Office (GAO) report that NSTS would be of little use to DOE in recovering and disposing of sources, the NSTS is not designed for this purpose and it would be impractical in terms of costs and benefits to alter it to serve the purpose. Reporting of unwanted sources is primarily a licensee responsibility. NRC works with the States, Council of Radiation Control Program Directors, the Organization of Agreement States, and DOE to secure unwanted or abandoned sources.

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As NRC commented to GAO, requiring the reporting of certain information which the report asserts DOE would find useful (e.g., frequency of source use) could be extremely burdensome on licensees and the NRC, and would yield little, if any, practical benefit. The NSTS will be of use to DOE in locating and recovering the most dangerous sources, those in Category 1 and Category 2 with the highest activity. Those sources account for approximately 86 percent of the total activity recovered by DOE. This is a risk-informed approach, consistent with NRC's regulatory philosophy.

It is also important to note that DOE, through its representatives on the NRC working group, steering group, and interagency coordination committee developing the proposed NSTS, has had the opportunity to provide input on the design of the system and the potential usefulness of the system to assist it in its source recovery program. DOE was provided a copy of the draft rule and sent it out to their facilities. They and other stakeholders have had an additional opportunity to comment on these and other issues raised in the notice of proposed rulemaking published July 28, 2005.

2. pp. 12-14 - At the end of FY 2004, the Interim Database had about 5,000 Category 1 and Category 2 sources, rather than the 3,600 cited in the OIG report. It presently has over 15,700 sources. Reporting has improved over time but it continues to be voluntary until the final rule requiring reporting is in effect.

On p. 13, the report states that "NRC cannot reasonably estimate the number of radioactive sources in the United States for each of the Code of Conduct categories." The staff disagrees; the information available in the Interim Database has improved and is certainly adequate for the present purpose of designing the NSTS. It would not be possible to have more precise or extensive information on sources without the mandatory reporting which will be required by the final rule.

3. p. 18, lines 13-16; p. 20, lines 20-22 - We suggest replacing these three sentences with the following: "NRC has considered the full range of radioactive sources that must be accounted for and based on its risk-informed approach to the safety and security of radioactive sources, has decided to track the Categories 1 and 2 sources recommended in DOE/NRC joint studies and the IAEA Code of Conduct. A tracking system will improve source accountability and foster greater control over radioactive sources. It will help deter and detect source loss or theft, reducing the possibility of use in an RDD, but it will not, itself, provide any additional physical security."

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Appendix C

DETAILED OIG RESPONSES TO AGENCY COMMENTS

At an exit conference on December 6, 2005, NRC provided informal, written comments on the draft audit report. OIG incorporated the suggestions as appropriate. On December 20, 2005, OIG audit staff met with agency officials and further discussed the report. On January 9, 2006, OIG issued a formal draft report and on February 1, 2006, NRC provided formal written comments (see Appendix B). OIG's responses to NRC's formal written comments are provided after each NRC comment. The main point of OIG's report, which is reiterated in each of OIG's responses, is that the agency's regulatory analysis for the National Source Tracking System rulemaking is based on unreliable data and does not include viable options.

Note: The page numbers used in NRC's comments do not correspond with the page numbers in this report because of line spacing differences between the draft report and the final report.

NRC General Comment 1

The Office of the Inspector General (OIG) notes that "The overall purpose of this audit was to determine whether NRC's oversight of byproduct and sealed source materials provides reasonable assurance that licensees are using the materials safely and account for and control the materials." The OIG and staff agree that the National Source Tracking System (NSTS) is one of many elements of the overall program to ensure that appropriate controls are implemented around the use of radioactive materials. With respect to Category 3 sources, the existing regulatory controls include the comprehensive health and safety and environmental measures of licensing, inspection, and reporting. As many as half of Category 3 sources are individually tracked in the General License Tracking System and the remaining Category 3 sources are specifically licensed. All Category 3 sources held by the DOE meet DOE's "accountable sealed radioactive source" criteria and therefore are inventoried and are subject to added reporting requirements.

NRC has issued orders for additional security measures to certain materials licensees with quantities of radionuclides of security concern. The orders took into account aggregation and co-location of material. These measures, rather than the NSTS, are directly concerned with the protection of material to preclude its use in the kind of RDD scenarios suggested on pp. 18 and 19 of the draft OIG report.

OIG Response

OIG agrees with the staff comment that security orders consider aggregation and as such address certain RDD scenarios. However, the staff comments fail to address the fact that movement of sources in commerce presents opportunities for covert diversion and aggregation. The security orders do not address these circumstances.

OIG is not recommending in its report that the NSTS necessarily include aggregation of curie quantities. Rather, the report highlights the issue of NRC's failure to evaluate aggregation as an option in the regulatory analysis. As such, a viable option has been eliminated from consideration without a supporting analysis.

OIG also notes that materials licensees currently have possession limits established in their licenses based on aggregate curie content of each respective radioactive isotope. As a factual matter, licensees must track the aggregate quantity of radioactive materials to ensure current compliance with these possession limits. As a practical matter, licensees should know the aggregate curie quantities of materials removed or added to their inventories in transactions. This reality indicates that an aggregate tracking system is a practical and viable option for consideration.

NRC General Comment 2

The decision of whether or not to include Category 3 sources in the upcoming rulemaking is pending before the Commission and continues to be addressed by the staff and by the Radiation Source Protection and Security Task Force established by the Energy Policy Act. While the Regulatory Analysis does not include a thorough examination of the costs and benefits of including Category 3 sources, the issue has previously been addressed by the staff, the Working Groups, the Interagency Coordination Committee, and the Steering Committee for NSTS, and it is discussed at length in the Federal Register Notice for the proposed rule.

The Commission has reviewed the NSTS rule and the planned system and approved publication of the proposed rule (70 FR 43646, July 28, 2005). There continues to be discussion of whether and how to include Category 3 sources. That remains an open question for the future but to include them now would greatly delay deployment of the system, possibly diminishing health, safety, and security and failing to fulfill the Nuclear Regulatory Commission's (NRC) commitments to Congress, other Federal and State agencies, and the International Atomic Energy Agency (IAEA). The staff is planning to send the Commission a paper concerning sources below Category 2, including generally licensed sources, in March. The NSTS has been designed so that its basic architecture will accommodate Category 3 sources if the decision is made to eventually include them.

OIG Response

The OIG report does not recommend a specific IAEA category for a cut-off point. As with aggregation, the central point of the OIG report in this regard is that the regulatory analysis fails to evaluate tracking at all of the Code of Conduct categories (1-5). As such, viable options have been eliminated from consideration without a supporting cost benefit analyses.

In addition, as noted above, NRC licensees must not exceed their possession limits and as a practical matter must track sources beyond categories 1 and 2.

NRC General Comment 3

Staff is now assessing the comments on the pending rulemaking. In parallel, staff is examining a range of options for improving the overall program to ensure appropriate controls for sources below Category 2. These options include specifically licensing all Category 3 sources by placing activity limits on general licenses, creating an inventory requirement for all Category 3 and above sources, and requiring source tracking for some sources below Category 2. The staff will weigh the costs and benefits of any proposed action and any option that includes rulemaking will include a regulatory analysis.

OIG Response

The agency's comments support the OIG report recommendation that the staff review all viable options in the NSTS regulatory analysis prior to promulgating the final rule. As noted in the OIG report, the purpose of a regulatory analysis is to ensure that NRC's regulatory decisions support its statutory responsibilities and are based on adequate information. Identifying and evaluating alternative approaches is a key element in meeting the letter and spirit of NRC's regulatory analysis policy.

Promulgating a rule with a regulatory analysis that does not address viable options is inconsistent with the basic precepts of effective and efficient agency rulemaking.

NRC General Comment 4

The Energy Policy Act of 2005, in Section 170H, establishes an interagency Task Force on Radiation Source Protection and Security, chaired by Chairman Diaz, and directs it to report to Congress and the President on recommendations for, among other matters,

- "modifications to the national tracking system for radiation sources;"
- "the establishment of, or modifications to, a national system (including user fees and other methods) to provide for the proper disposal of radiation sources secured under this Act;"

The Task Force, including most of the same agencies that were involved in the development of the NSTS, will be dealing with concerns on the NSTS at a high level and can be expected to make recommendations that resolve policy questions such as those raised in the OIG report.

OIG Response

The overarching issued raised in the OIG report is that the staff did not conduct a thorough regulatory analysis of all relevant factors associated with the NSTS. NRC should not leave this important function to the interagency Task Force on Radiation Source Protection and Security.

NRC General Comment 5

SRM-SECY-05-0201, "Implementation Of the Energy Policy Act of 2005" requires the staff to again consider including Category 3 sources in the NSTS:

> "6. Section 651(d)(1) Radiation Source Protection, National Academy of Sciences Study - This section in the Energy Policy Act contains the definition of 'Radiation Source,' part B of which states 'any other material that poses a threat such that the material is subject to this section, as determined by the Commission, by regulation....' The staff has asked for comments on the inclusion of Category 3 sources, or an appropriate subset of Category 3 sources, in the National Source Tracking System (NSTS) and the staff should carefully consider those comments. If, ultimately, Category 3 sources are not included in the NSTS rule, the staff should consider doing so in a separate rulemaking and either develop a schedule and cost for this rulemaking or document in some manner that a separate rulemaking is not needed and the rationale for this statement."

OIG Response

This report does not focus solely on NRC including Code of Conduct Category 3 sources in the NSTS. Rather, OIG is recommending that the agency conduct the necessary regulatory analysis to determine which Code of Conduct categories should be tracked in NSTS. Additionally, NRC's regulatory analysis should consider aggregation of sources and bulk material.

NRC General Comment 6

The identification of materials of hazard in the Department of Energy (DOE)/NRC Joint Report on "Radiological Dispersal Devices" (RDDs) was intended to guide assessments regarding a system to track sources. The results can be used to define the NSTS population and future tracking priorities.

The NRC action threshold defined in the DOE/NRC RDD report included consideration of respirable and release fractions. This threshold roughly equates to the IAEA Category II definition.

OIG Response

The RDD study did not recommend limiting the National Source Tracking System to Category 1 and 2 sources. Insights gained from the RDD report should be included in the regulatory analysis.

NRC Specific Comment 1

p. 10, lines 23-26; p. 11, lines 1-4 - With reference to the citation of the U.S. Government Accountability Office (GAO) report that NSTS would be of little use to DOE in recovering and disposing of sources, the NSTS is not designed for this purpose and it would be impractical in terms of costs and benefits to alter it to serve the purpose. Reporting of unwanted sources is primarily a licensee responsibility. NRC works with the States, Council of Radiation Control Program Directors, the Organization of Agreement States, and DOE to secure unwanted or abandoned sources.

As NRC commented to GAO, requiring the reporting of certain information which the report asserts DOE would find useful (e.g., frequency of source use) could be extremely burdensome on licensees and the NRC, and would yield little, if any, practical benefit. The NSTS will be of use to DOE in locating and recovering the most dangerous sources, those in Category 1 and Category 2 with the highest activity. Those sources account for approximately 86 percent of the total activity recovered by DOE. This is a risk-informed approach, consistent with NRC's regulatory philosophy.

It is also important to note that DOE, through its representatives on the NRC working group, steering group, and interagency coordination committee developing the proposed NSTS, has had the opportunity to provide input on the design of the system and the potential usefulness of the system to assist it in its source recovery program. DOE was provided a copy of the draft rule and sent it out to their facilities. They and other stakeholders have had an additional opportunity to comment on these and other issues raised in the notice of proposed rulemaking published July 28, 2005.

OIG Response

OIG is aware of the working relationship that NRC has with the States, Council of Radiation Control Program Directors, the Organization of Agreement States, and DOE regarding the securing of unwanted sources. OIG is not suggesting in its report that NSTS be used for the purpose of securing unwanted sources. However, the report does call to attention that because aggregation or the co-location of sources is not being considered for NSTS, the combined activity posed from individual sources (above the Code of Conduct Category 2 threshold) may still pose a safety and security risk. Refer to Figure 3 in the body of this audit report for a diagram showing the potential results if aggregation is not considered in NSTS. While NRC states its decision is made using a risk-informed approach, evidence of this "approach" is not provided in the NSTS regulatory analysis.

The report text remains unchanged.

NRC Specific Comment 2

pp. 12-14 - At the end of FY 2004, the Interim Database had about 5,000 Category 1 and Category 2 sources, rather than the 3,600 cited in the OIG report. It presently has over 15,700 sources. Reporting has improved over time but it continues to be voluntary until the final rule requiring reporting is in effect.

On p. 13, the report states that "NRC cannot reasonably estimate the number of radioactive sources in the United States for each of the Code of Conduct categories." The staff disagrees; the information available in the Interim Database has improved and is certainly adequate for the present purpose of designing the NSTS. It would not be possible to have more precise or extensive information on sources without the mandatory reporting which will be required by the final rule.

OIG Response

OIG cited 3,600 sources in the report because that is the number that agency staff used in developing the NSTS Regulatory Analysis (see page 7, section 3.2.2.2 of the NSTS Regulatory Analysis). As NRC clearly points out in its comment, the data used from the Interim Database to develop the NSTS Regulatory Analysis is unreliable. At the time the NSTS Regulatory Analysis was being developed, the staff used data from the Interim Database which contained approximately 23 percent of the estimated 15,700 Category 1 and/or 2 sources. NRC's comment further validates OIG's recommendations.

The Interim Database contains data on Code of Conduct categories 1 and 2 sources. Therefore, NRC has no scientifically reliable means of determining the number of sources in categories 3, 4, and 5, based on estimates of the sources in categories 1 and 2.

The report text remains unchanged.

NRC Specific Comment 3

p. 18, lines 13-16; p. 20, lines 20-22 - We suggest replacing these three sentences with the following: "NRC has considered the full range of radioactive sources that must be accounted for and based on its risk-informed approach to the safety and security of radioactive sources, has decided to track the Categories 1 and 2 sources recommended in DOE/NRC joint studies and the IAEA Code of Conduct. A tracking system will improve source accountability and foster greater control over radioactive sources. It will help deter and detect source loss or theft, reducing the possibility of use in an RDD, but it will not, itself, provide any additional physical security."

OIG Response

The OIG has considered this proposal but has chosen to maintain the passages in the report. Although the staff may have considered a range of sources that should be accounted for, such options have not been explored or documented in the regulatory analysis. In addition, although the staff states that the approach is risk-informed, OIG has not been presented with any documentary evidence of a risk assessment. OIG has not been presented with any form of analysis supporting the claim that the cost and burden of tracking sources in categories 3, 4, and/or 5 are not justified. The only supporting evidence included in the rulemaking is unsupported statements to that effect as well as anecdotal representations from commenters. This is not sufficient for the OIG to adopt the proposed wording changes recommended by the staff.

The report text remains unchanged.