Evolution of the National Materials Program

Introduction

This enclosure summarizes the evolution of the National Materials Program in the United States. The National Materials Program includes the U.S. Nuclear Regulatory Commission (NRC) and Agreement State materials programs. It focuses on significant milestones in the evolution of the program, and also provides a history of the resource effects from 2000 to present, as requested in Staff Requirements Memorandum (SRM) SRM-M160225B.

The NRC materials program was initially developed within the Atomic Energy Commission (AEC) beginning in the 1950s. Although a regulatory program to ensure the safe use of radioactive materials existed from the beginning, after the enactment of the Atomic Energy Act of 1954, the early years of the program were significantly influenced by the national program to promote the use of radioactive materials. This latter program gained new momentum with President Eisenhower's "Atoms for Peace" speech to the United Nations General Assembly in 1958. As described in this enclosure, the resource aspects of the NRC's materials program refers to the Nuclear Materials Users business line.

History of the Program

During the early years of the program, the AEC authorized a wide variety of civilian organizations to use radioactive materials with minimal review effort in support of licensing. AEC placed a heavy onus on the licensees to accomplish radiation protection through compliance with the radiation protection standards in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20. Licensing standards for byproduct material (Part 30), source material (Part 40), and special nuclear material (Part 70) were relatively general with the primary emphasis on ensuring that licensees had suitably qualified staff, controls, and procedures in place to ensure safety. In addition to the license requirements, civilian organizations faced other requirements through contracts administered by the AEC to gain access to radioactive material and to support government-sponsored research, development, and other operations. The anthology of NRC regulations in Appendix A reflects the initial development of these licensing requirements in the 1950s and 1960s. As AEC and the NRC gained operating experience through normal operations, event response, and technological innovation, the agencies developed and issued more detailed and specific regulations.

The First Agreement (1962)

Congress amended the Atomic Energy Act in 1959 to authorize the Agreement State program in response to strong and persistent interest expressed by the states in regulating atomic energy. In the years after the amendment, Kentucky and New York emerged as front-runners by actively pursuing agreements with the AEC. When Kentucky submitted its application, controversy arose over whether the State should regulate land disposal of radioactive waste, as well as the manufacture and distribution of products containing radioactive material. In an effort to resolve these issues and move forward with the agreement, a compromise was reached in which the State would regulate disposal and devices with radioactive material, except for consumer products (a.k.a., exempt distribution products).

Kentucky successfully became the first Agreement State on March 26, 1962. By 1964, AEC had signed agreements with six States—Kentucky, California, Mississippi, New York, Texas, and Arkansas—and began annual meetings with the Agreement States.

Uranium Mill Tailings (1978)

Concerns about the potential health hazards associated with uranium mill tailings and questionable regulatory controls on the tailings led to Congressional hearings in the late 1970s. At that time, the AEC and later the NRC regulated the mills that produced uranium and thorium tailings because they possessed source material, but the government's authority to regulate the tailings remained somewhat uncertain. The uranium mill tailings contain both radioactive and chemical wastes left over from the processing of uranium ore to recover uranium and other valuable elements. Lax controls over the tailings allowed their use as backfill in thousands of locations including building foundations, water and sewer lines, roadbeds, and baseball infields, exposing members of the public to elevated dose rates and radon. These concerns compelled Congress to enact the Uranium Mill Tailings Radiation Control Act of 1978 as an amendment to the Atomic Energy Act.

The evolution of uranium mill regulation included explicit expansion of authority for the NRC to regulate uranium and thorium byproduct materials. It also established the need for explicit guidelines for periodic review of Agreement State programs. In 1981, the NRC published a policy statement on evaluation of Agreement State programs, after development and review by the Agreement States.

Low-Level Waste (1979)

The next significant milestone in the materials program occurred in 1979 with the low-level radioactive waste crisis that ultimately led to the Low-Level Radioactive Waste Policy Act of 1980 and the Low-Level Radioactive Waste Policy Amendments Act of 1985. In 1970, there were five low-level waste disposal facilities in five Agreement States. In addition, there was one disposal facility (Sheffield, IL) in a Non-Agreement State. These facilities were regulated generally under broad authority for possession of materials under 10 CFR Parts 20, 30, 40, and 70, and without detailed regulations for waste disposal and associated handling. By the end of the 1970s, only Barnwell, Beatty, and Richland were open for commercial waste disposal. These three disposal facilities may have sufficed in meeting the Nation's needs, but several noteworthy developments occurred:

- growing awareness of the need to protect the environment and concerns about the adequacy of solid waste disposal in general

- degraded conditions (collapsed covers, water ponding in trenches, contamination of the environment) at the other three radioactive waste disposal facilities that were no longer operating

- banning disposal at Barnwell of low-level waste generated from the cleanup of the accident at Three Mile Island Unit 2, along with wastes containing organic liquids

- lack of specific regulations governing the adequacy of shallow land burial of radioactive waste

- waste packaging problems in transportation and at the disposal sites that prompted negative public perceptions of the safety of radioactive waste disposal

Congress enacted the Low-Level Radioactive Waste Policy Act based on several fundamental concepts:

- that each state should be responsible for managing its own disposal capacity
- that low-level waste could be most effectively and efficiently managed on a regional basis
- that States could enter into regional compacts to collectively accomplish the necessary disposal capacity

Additionally, in January 1981, the NRC revised its criteria for entering into agreements to include low-level waste disposal as a separate category for the agreements under Section 274 of the Atomic Energy Act. The NRC took this action in anticipation of potential interest by States in seeking a 274b agreement solely for the purpose of commercial disposal of low-level waste with the establishment of a regional compact.

The NRC has remained focused on its role as a regulator to ensure safety, security, and environmental protection. The NRC and the Agreement States succeeded in improving cooperation by resolving regulatory issues involving low-level waste management, recognizing low-level waste disposal as a separate category of regulated activities under Section 274, and facilitating communications and limited progress through workshops, meetings, and guidance development.

Integrated Materials Performance Evaluation Program (IMPEP, 1993)

The growth of Agreement State licenses is depicted in Figure 1.

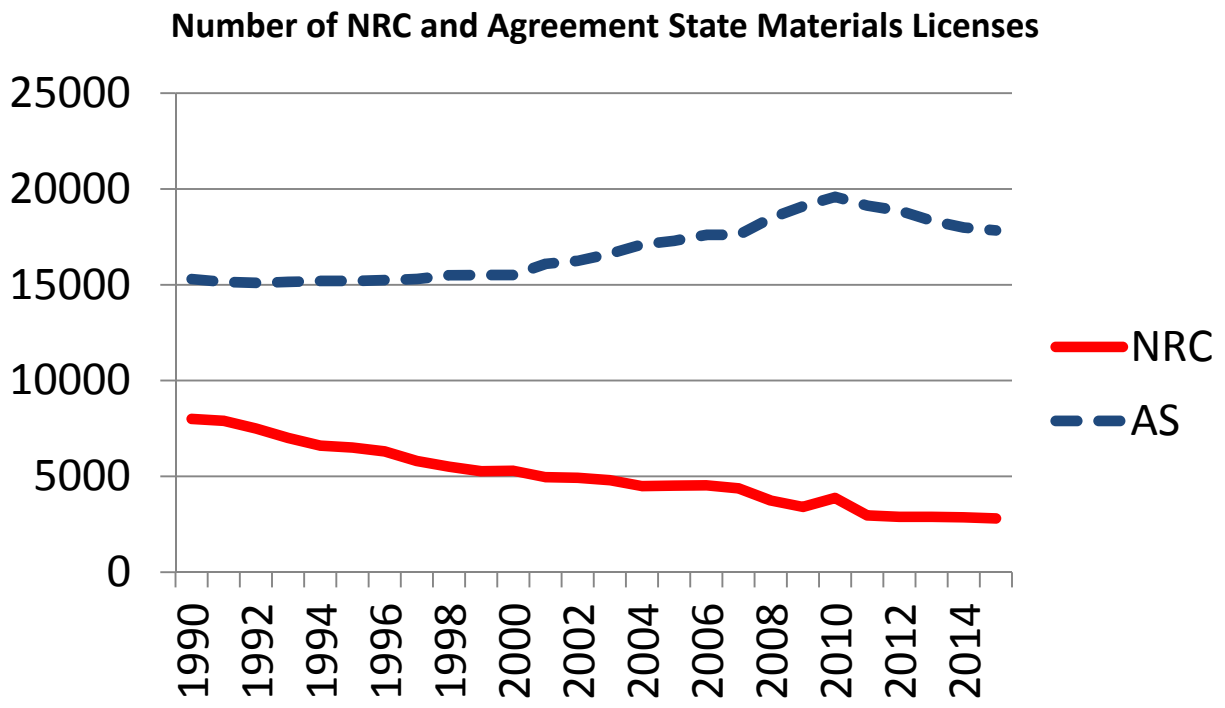

Figure 1. Number of NRC and Agreement State materials licenses.

Congressional interest in the role of the Agreement States paved the way for a 1993 audit in which the U.S. Government Accountability Office (GAO) concluded that the NRC was inconsistent in evaluating the effectiveness of the NRC and Agreement States' materials regulatory programs with respect to the goal of adequately protecting the public. GAO issued its report "Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials" (GAO/RECD-93-90) in April 1993. In the report, GAO recommended the establishment of common performance indicators to evaluate the effectiveness of both Agreement State and NRC programs, along with specific procedures for suspending or revoking an Agreement State's authority for a program. In addition, GAO recommended that Agreement States be required to report abnormal occurrences and that events in Agreement States be reported more completely and accurately.

In response to the GAO report and subsequent Congressional meetings, the Commission directed the staff to address the issues that were raised, including

- improvements in guidance and principles of operation
- action levels for top management and Commission involvement
- reciprocity under NRC and Agreement State programs
- codification of the State Agreement practices

This ultimately led to the NRC placing more emphasis on fostering stronger relationships with the Agreement States through greater structure, predictability, consistency, and rigor, as well as a stronger emphasis on program performance. These insights were ultimately captured in the IMPEP. Today, the NRC and Agreement State representatives work side by side in a partnership in conducting reviews of Agreement State and NRC programs. IMPEP also provided a more open and transparent process for the determination of the adequacy and

compatibility of materials regulatory programs. The NRC conducted a self-assessment of the IMPEP 15 years after its establishment and reported the results at the Organization of Agreement States (OAS) Annual Meeting in 2010. Although the program is continuously being refined by the NRC and the Agreement States, it is viewed by the States and the NRC (and other Federal agencies) as a model for effective and efficient Federal-State cooperation.

Business Processing Re-Engineering (1994)

Throughout most of the 1990s, the NRC's budgets contracted, as workload decreased in the materials program as new Agreement State programs were established. In 1993, Congress issued the Government Performance and Results Act, requiring Federal agencies to enhance strategic planning and performance management. As a coping approach, the NRC began to reconsider its existing materials program in the mid-1990s to boost performance and increase efficiency. Business Process Re-engineering (BPR) was identified as the primary method to accomplish these goals.

The BPR findings included:

- The NRC's licensing processes were largely undefined and were not synchronized or consistent with those used by the Agreement States.
- The NRC's escalating fee structure under the Omnibus Budget Reconciliation Act of 1990 was unfair and unrealistic.
- Licensing guidance was outdated and was not easy to access or use because it was not consolidated.
- Some materials licensees did not completely understand the NRC licensing process.
- Rulemakings were time-consuming.

These findings provided the foundation for establishing the consolidated materials guidance in NUREG-1556, "Consolidated Guidance about Materials Licenses," in partnership with the Agreement States. To free up resources to devote to developing and issuing the guidance, the NRC administratively extended the license expiration dates by 5 years (from 5-year terms to 10-year terms), doubling the duration of the licenses and saving multiple full time equivalents (FTE) by deferring the workload that would have otherwise been required to review and approve the licenses.

In 2000, the NRC launched the Byproduct Material Review. This effort focused more broadly on the materials regulatory program and was intended to identify, assess, and recommend changes to further improve efficiency and effectiveness, apply a more rigorous risk basis for supporting program decisions, and help control or reduce annual fees. In 2001, the review was completed with the conclusion that the materials "program is at a crossroads." Although some efficiencies had been accomplished since the BPR project, the large number of materials licenses multiplied by the unit costs of licensing reviews, inspections, incident responses, rulemakings, enforcement, investigations, and other regulatory actions would continue to require a sustained amount of resources, absent fundamental improvements in the efficiency of the NRC's processes.

The Byproduct Material Review report recommended short-term and longer-term improvements to the materials regulatory program. The authors of the report ensured that the recommendations were "resource neutral," so that the intended savings to be gained by implementing the recommendations would be at least as large as the investment required for the recommendations to be implemented. Unfortunately, the report was completed and distributed within the NRC and with the Agreement States only weeks before the terrorist attacks on September 11, 2001.

National Materials Program (2000)

The concept of a "National Materials Program" emerged in the late 1990s. Financial constraints in the materials program throughout the 1990s and the recovery of the NRC's budget through annual fees and fees for service helped to sharpen the NRC's focus on the National Materials Program during the 1990s.

In March 2000, the NRC and the States formed a working group to consider the potential effects of the increasing number of Agreement States and the decreasing number of NRC material licensees, as well as to provide advice on the National Materials Program. The working group completed its report in May 2001 and recommended that the NRC and States adopt a cooperative process to identify, prioritize, and address the regulatory needs of the program. This included specific recommendations that have been subsequently implemented, including:

- seek authority to regulate Naturally Occurring and Accelerator Produced Radioactive Material (NARM)
- develop and maintain an information infrastructure
- create a standing compatibility committee

The NRC and the States have made progress in establishing a common set of priorities where the NRC reports to Congress, and the Agreement State agencies report to State legislatures. These challenges have intensified during the last decade because of heightened fiscal constraints and emergent work, such as the substantial increase in work associated with enhancing source security in the aftermath of the 9-11 terrorist attacks.

The NRC and States have enhanced the partnership by actively involving each other in working groups to draft regulations and guidance, resolve regulatory issues, and determine the most effective and efficient approaches while preserving the flexibility for each to accomplish success within their respective frameworks and means. IMPEP has helped to keep the agencies focused on safety and security. The NRC and States have also enhanced this partnership through improved communication and coordination. The list of successes includes implementation of the National Source Tracking System (NSTS), increased controls, radiological criteria for decommissioning, uranium mill tailings stabilization, radiographer certification, and other important initiatives. This partnership is strengthened by the effective working group on compatibility for rulemakings and guidance development.

Increased Controls (2005)

The 9-11 terrorist attacks refocused government and public attention on the security of radioactive sources. Although the attacks did not directly involve radioactive material, they helped the NRC, other government agencies, and the States to recognize the substantial

increase in the threat environment and the prospect that terrorists or other adversaries could have the motivation and the means to use radioactive sources malevolently in a Radiological Dispersal Device or a Radiation Exposure Device. The Commission decided, with strong support from Congress, other departments and agencies of the Federal Government, and international agencies, that enhancements were needed to the control of radiation sources, particularly those that posed the highest risk of malevolent use. These sources are designated by the International Atomic Energy Agency as Category I and II sources.

As the plans for imposing security requirements took shape within the NRC, the NRC developed and issued security orders to large commercial irradiators in June 2003 and manufacturers and distributors of sources in January 2004 under the Commission's common defense and security authority. In deliberating on whether to issue orders, the Commission considered a variety of approaches, but ultimately elected to issue the orders based on timeliness, consistency, and effectiveness considerations.

In June 2004, the NRC offered an opportunity to the Agreement States to perform inspections for and on behalf of the NRC on licensees in Agreement States by entering into Section 274i Agreements. The NRC subsequently issued its Increased Controls order to about 500 NRC licensees on November 14, 2005. That order was published in the *Federal Register* on December 1, 2005. The Agreement States successfully completed issuance of the Increased Controls to about 1,700 licensees under the health and safety provisions of their respective agreements in November 2005 as well.

Congress enacted the Energy Policy Act of 2005 as part of a much broader portfolio of legislation redefining the National Energy Strategy in the aftermath of 9-11. This law established a number of requirements, new authorities, and incentives associated with nuclear power, radioactive sources, and nuclear security. Relevant to the National Materials Program, the Energy Policy Act of 2005 accomplished a number of enhancements, including:

- broadening the definition of byproduct material to include discrete sources of radium-226 and accelerator produced radioactive material
- prohibiting the export and import of radiation sources unless conducted in accordance with NRC requirements
- requiring the establishment of a mandatory tracking system for Category I and II radioactive sources
- tasking the National Academy of Sciences study on alternatives to radiation sources for industrial, research, and commercial uses
- establishing the Task Force on Radiation Source Protection and Security, led by the NRC Chairman and in consultation with OAS and the Conference of Radiation Control Program Directors (CRCPD)
- requiring fingerprinting and a background check of any individual with unescorted access to certain radioactive material or safeguards information

GAO Sting Operation (2007)

The decisions on how far to go in requiring safety and security enhancements through the increased controls were based on comprehensive and balanced assessments of the vulnerabilities and threats associated with radioactive sources. Throughout these assessments, however, the NRC maintained the assumption that license applicants could be trusted until proven otherwise based on their actions. This was called the "good faith" presumption.

The vulnerability of this presumption was exposed in late 2006 and early 2007, when the GAO conducted a test to see if they could fraudulently obtain a license for radioactive material and subsequently purchase the material. This test was referred to as the "GAO Sting Operation." The NRC issued a license to a fraudulent company. GAO modified the license by increasing the possession limit and then used the modified license to receive quotes for purchasing the radioactive materials from several companies.

The Senate Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations held a hearing on July 12, 2007, that featured the 2007 GAO sting. In response to questions from the committee, the NRC acknowledged that information technology could be used to reduce this vulnerability and the likelihood of fraudulent applications or modified licenses. As a result, the NRC collaborated with the States and implemented a comprehensive action plan outlining a number of steps to enhance controls on radioactive sources and licensing, including a portfolio of computer tools for license verification and tracking of licenses and certificates, inspections, sources and devices, and events. These tools are known as the Integrated Source Management Portfolio, a suite of programs that includes: the NSTS, the Web-based Licensing System (WBL), and the License Verification System (LVS).

The NRC successfully deployed the NSTS in 2008, which today tracks about 1,400 Agreement State and NRC licensees who possess about 77,000 sources. The WBL was completed and deployed in 2012. The NRC was able to substantially compress the time between project start and system implementation thanks to Ohio's sharing of its RADNET licensing program, which the NRC modified so it can be used by any radiation program for licensing and inspection. The NRC began implementing the Web-based version of License Tracking System in 2010 and then formally implemented the WBL in 2012. Several Agreement States also adopted WBL for implementation in the years that followed. The LVS was implemented in 2013.

The NRC and the Agreement States realized that the good faith presumption is no longer appropriate when terrorists and other criminals are willing to go to extreme lengths. By working together on the development and refinement of a comprehensive IT infrastructure and other enhancements, the NRC and the States have strengthened the partnership by sharing best practices and tools.

Financial Analysis

Historical data was closely examined for fiscal years (FY) 2000 through FY 2015. Although reporting systems and levels of detail varied through the years, a few notable trends emerged that help to chronicle the change in resources through that period of time. Additionally, the causes for resource increases and decreases have been compiled into Appendix B, to help provide perspective on the regulatory environment which led to the budgetary requests, and actual spending.

Overall Program Resource Trend

As shown in Figure 1, the number of NRC materials licensees has steadily decreased while the number of Agreement State licensees has increased. Between FY 2000 and FY 2015, the number of NRC materials licensees has decreased from 5,288 to approximately 2,800. The steady decline in number of licensees has been expected, as six states became new Agreement States (Oklahoma, 2000; Wisconsin, 2003; Minnesota, 2006; Pennsylvania, 2008; Virginia, 2009; and New Jersey, 2009) accompanied by licensee transfers from the NRC to Agreement State oversight. During that same period of time, the NRC materials program FTE (i.e., not including overhead) has decreased from 292 FTE in FY 2000 to 251 FTE in FY 2015. Figure 2 plots the number of NRC materials licensees with the program FTE and program support costs.

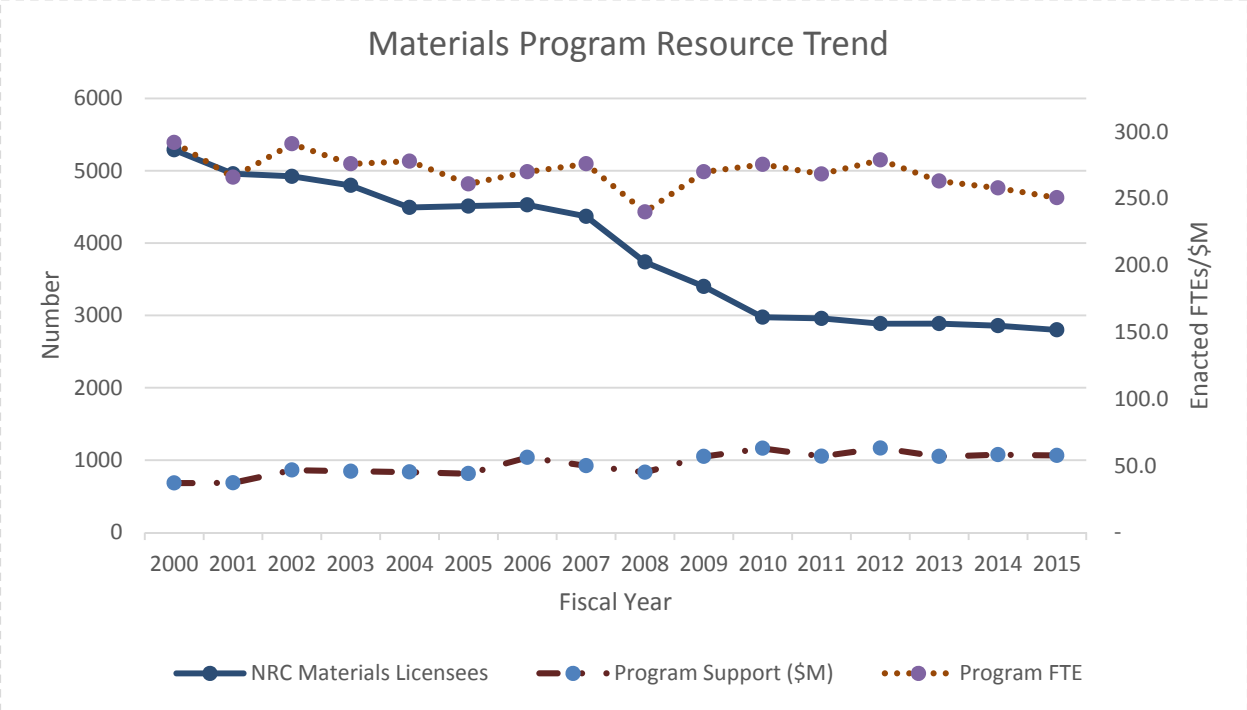

Figure 2. Number of NRC materials licensees with corresponding Enacted Program FTE and support costs since FY 2000

The NRC program FTE continues to decrease, though not at the same rate as the decrease in number of materials licensees. There are a number of causes that contribute to these differing rates, and for the program support costs increase in that period of time. Appendix B documents the specific causes for resource increases every year. Some of the major contributing causes for resource increases and decreases include the program enhancements implemented because of: (1) increased controls in response to the 9-11-2001 terrorist attacks, (2) GAO report, “Nuclear Security: Federal and State Action Needed to Improve Security of Sealed Radioactive Sources,” GAO-03-804, and subsequent GAO “sting” in 2007, (3) transition to performance-based inspections, and (4) transfer of materials licensees from the NRC to Agreement States.

Additionally, it is important to note that although the introduction of new Agreement States generally decreases the overall resource requirement from the NRC over time, the initial transfer of licensees from the NRC to the new Agreement State actually increases resource needs in the short term to account for programmatic, licensing, and oversight activities necessary to process a transfer.

The program support costs have gradually increased since FY 2000 due to spending that has been necessary to continue to provide the oversight and accountability of source security. This includes systems developed for the NSTS, WBL, and LVS. Additionally, the increasing number of Agreement States has led to increased spending needs to provide oversight and collaboration to Agreement State partners, including restoring historic funding levels for the CRCPD, funding the triennial meeting with governor-appointed State Liaison Officers, and training costs for Agreement State participation.

A more focused review of the FTE trend was conducted for Region I, because of its relatively recent history of having been affected by the transfer of a large number of materials licensees to new Agreement States in 2008 and 2009. Between 2008 and 2009, Pennsylvania, Virginia, and New Jersey all became Agreement States, and completed the transfer of approximately 1,600 materials licensees away from the NRC. This shift in oversight and licensing responsibility was reflected in the following years with decreases in FTE for the Region I materials program. The Region I materials program dropped from approximately 55 FTE in FY 2007 to 44 FTE in FY 2011. The decreasing trend is confirmation that the materials program did compensate for a decreased number of licensees by adjusting FTE. The magnitude of decrease was counteracted by the increasing level of effort and complexity required for inspection and licensing actions and is further described in the Licensing Resource and Inspection Resource sections below.

Licensing Resource Trend

A major driver for program FTE is licensing activities, both in number of actions, and scope of review. Both number and scope were evaluated since FY 2000, in comparison with the number of materials licensees and FTE expended. Figure 3 plots the number of NRC materials licensees with the completed licensing activities and actual staff hours spent on licensing.

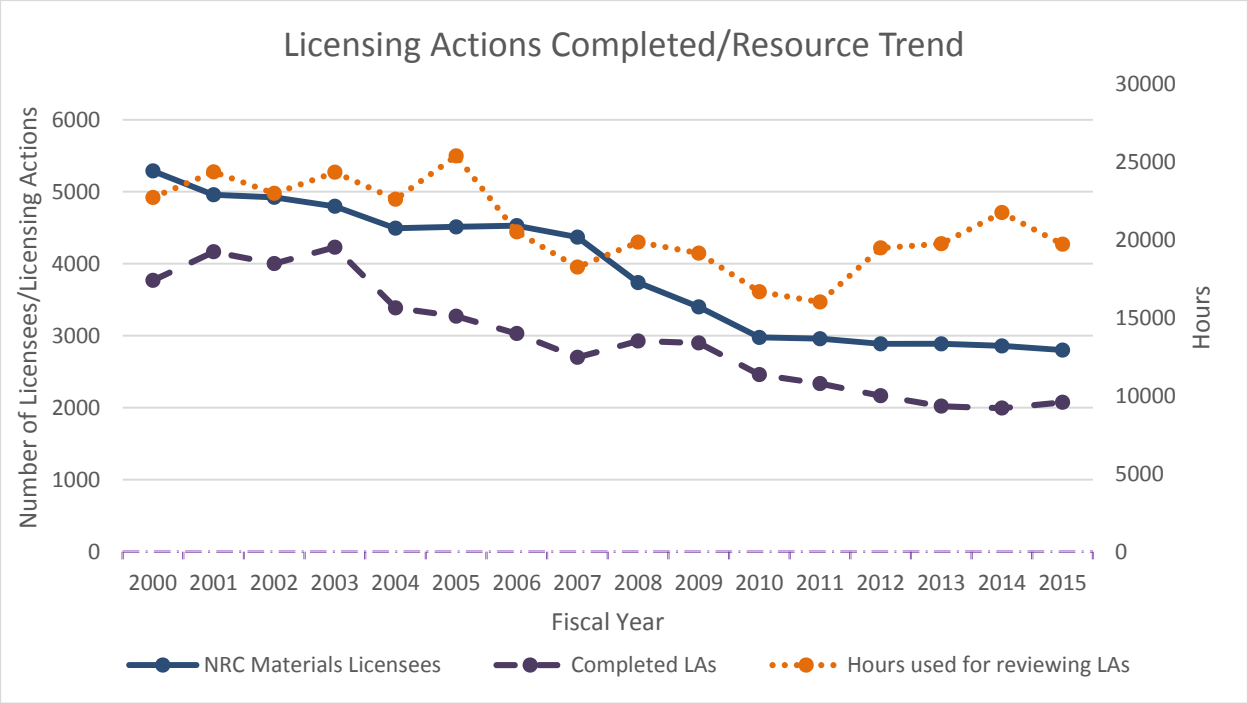

Figure 3. Number of NRC materials licensees with completed licensing activities and staff hours spent on licensing activities since FY 2000

As shown in Figure 3, the number of licensing activities completed has a decreasing trend, very closely following the decreasing number of NRC materials licensees. The number of licensing activities completed is representative of the total number of new applications, amendments, renewals, and sealed sources and device reviews. The matching decreasing trend lines are validation of the expected number of activities over time. However, it does not factor in changes to the scope of each of the activities.

The total effort spent on these licensing actions also has a matching decreasing trend in the early 2000s, before starting to trend up beginning around FY 2008, and increasing in recent years despite the overall decrease in number of materials licensees and licensing actions. A closer look at the major program factors, and the causes for resource increase in that period of time, highlights the 2007 GAO sting of the NRC licensing process. The vulnerabilities exposed by this 2007 GAO sting led directly to either the introduction of or renewed emphasis on several major resource intensive licensing process enhancements including: pre-licensing visits, development and implementation of a national registry of radioactive sources to improve the controls on radioactive materials through the NSTS, further development and expanded use of WBL, and development of NUREG-1556 guidance which increased the level of effort and complexity of licensing reviews.

The pre-licensing visits were implemented on a limited basis before 2006 and primarily involved large programs or programs that presented significant or unique safety technical issues. Pre-licensing visits were limited to Type A[1] licenses of broad scope; panoramic irradiators; manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material; radioactive waste brokers; radioactive waste incinerators; commercial nuclear laundries; and any other application that involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit. Pre-licensing visits were considered for amendments and renewal if the licensee was making significant changes to their programs. After the 2007 GAO sting, the NRC and Agreement States implemented a more widespread use of checklists and pre-licensing visits which required additional staff effort. The pre-licensing visit also determines that a license applicant is a known entity and, for risk significant quantities of radioactive material, allows for an on-site 10 CFR Part 37 security review. These requirements may not be satisfied with one trip, and could add a significant level of resources to the licensing process. This additional staff effort for pre-licensing visits partially explains the increased hour trend shown in Figure 3.

Inspection Resource Trend

Another major driver for program FTE is inspections. Both number and scope of inspections were evaluated since FY 2000, in comparison with the number of materials licensees and FTE expended. Figure 4 plots the number of NRC materials licensees with the completed inspections and actual staff hours spent on inspection support.

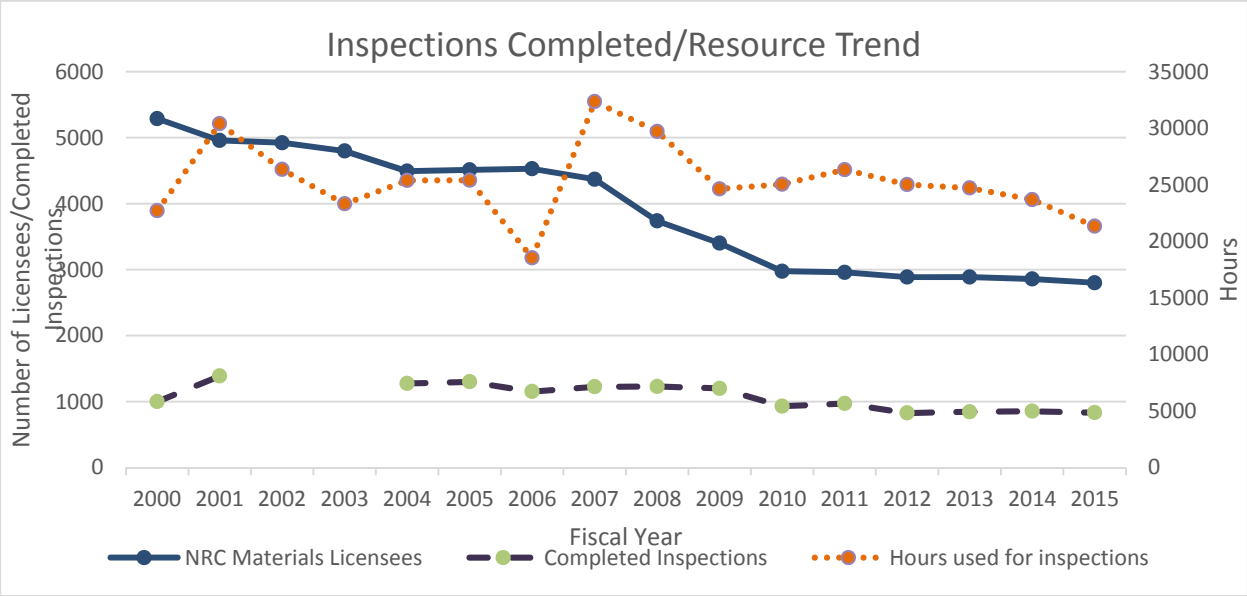

Figure 4. Number of NRC materials licensees with completed inspections and regional Hours spent used on inspection support since FY 2000.*

* Data for number of completed inspections in FY 2002 and FY 2003 is incomplete. The data point for Inspection hours in FY 2006 is believed to be artificially low because of changes in TAC mapping that year.

1 A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the byproduct material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the Act. The quantities specified are usually in the multicurie range.

As shown in Figure 4, the overall number of completed inspections decreases gradually. Additionally, aside from a temporary increase in FY 2008, the total effort required to conduct and support these inspections has stayed roughly flat. It should be noted that there is not a one-to-one correlation between the number of licensees and number of inspections. Some licensees have multiple locations, multiple users, and varying degrees of complexity. These inspections may require many more resources than a simple licensee. Some licensees require annual or more frequent inspections; other licensees can have a periodicity of several years. There were program changes that increased the number of field site inspections. Furthermore, additional requirements for the control of security-related and personally identifiable information were implemented that added to the administrative aspects of inspection planning and documentation that staff must now complete.

Post 9-11 activities in the early 2000s led to a few major programmatic enhancements which significantly affected the number and complexity of materials inspections. These include the issuance of increased control orders, which required training of inspectors, additional security inspections related to the Orders, and resource-intensive reviews with Headquarters staff for all findings. Additional administrative requirements for the control of security-related information were implemented that added to the complexity of inspection-related activities. In addition, in many cases the NRC staff was required to conduct security inspections, despite the licensees being in an Agreement State. Furthermore, the NRC reviewed and inspected multiple new medical devices under 10 CFR 35.1000, and significantly increased inspection efforts for Category 1 and 2 licensees because of 10 CFR Part 37, which expanded the effort, complexity, and necessary training for inspections.

The transitory increase of the FY 2007 staff hour inspection resource aligns with changes in the program corresponding to the 2007 GAO sting, along with ongoing source security improvements at the time. The temporary increase subsequently returned to previous levels, and has remained fairly steady since then. A flat trend for completed inspections and inspection effort indicates that, despite fewer materials licensees, the number and complexity of inspections has remained, with some exception, the same since FY 2000.

FY 2008 Budget Request

The FY 2008 Budget Request for Nuclear Materials Users requires further explanation because of its low estimates. The budget request for FY 2008 was unique in several ways. The program appears to have significantly underestimated the number of licensing actions for that year at 1,700 licensing actions, in comparison to the 4,400 actions estimated in FY 2007. Nonetheless, the program still ended up completing 2,926 licensing actions in FY 2008. Furthermore, FY 2008 represents a single year FTE dip from the year before and the year after (FY 2007, 276 FTE; FY 2008, 240 FTE; FY 2009, 270 FTE). Reasons for this dip are stated in the FY 2008 NRC Performance Budget statements below:

> *For FY 2008:*
> *Nuclear Material Users resources primarily decrease for homeland security activities including rulemakings, and for materials licensing reviews. Efforts for web-based licensing, and research support for human reliability issues and dose assessments are eliminated in FY 2008.*

The NRC will save resources in the materials inspection program by implementing a more risk informed set of inspection priorities and inspection procedures, focusing those resources more precisely on the types of facilities and licensee activities that are most critical to maintaining safe operation. The NRC's FY2008 budget request reflects these efficiencies.

When viewed more broadly, however, it is clear that the program's resource needs for completing the safety and security mission have been relatively stable over time.

Summary

The National Materials Program has evolved significantly since its inception in the early 1960s. Currently, the program encompasses thousands of licensees throughout the country, covering multiple critical infrastructure sectors. The program continues to evolve to meet the changing regulatory and budget climate. Over time, the number of Agreement States has risen and the number of materials licensees under NRC jurisdiction has decreased. Nonetheless, concurrent with the decrease in the NRC's materials licensees, there have been a number of external factors that have led to a restructuring of resources to address an increased level of oversight in some areas and a decrease in other activities. Some notable examples include: the need for increased nuclear material security oversight; emerging medical technologies; an increased number of permanently shut down reactors and complex materials sites requiring decommissioning oversight; new requirements and authorities established by the Energy Policy Act of 2005; significant fluctuations in the price of uranium and its effect on uranium recovery facilities; and support by the regional materials program staff for emergency response activities, including Continuity of Operations. Despite an ever-changing landscape, the National Materials Program has successfully met these challenges by cross-training staff in multiple disciplines; reallocating staff resources to focus on emerging issues; enhanced communication and coordination with Agreement State representatives; and other program enhancements to stay right-sized, efficient, and effective. This forward-thinking strategy has served the program well for decades and continues to be viewed by the States, other Federal agencies, and international counterparts as a model program for effective and efficient regulatory oversight.

Appendix A—Anthology of NRC Regulations for the Materials Program

Year	Significant Events	Regulation
1956		Part 30—Licensing of Byproduct Material; Part 50—Domestic Licensing of Production and Utilization Facilities; Part 70—Domestic Licensing of Special Nuclear Material
1957	Overexposures in fabricating ^{192}Ir sources in Houston, Texas (March)	Part 20—Standards for Protection Against Radiation
1958		Part 71—Regulations to Protect Against Accidental Conditions of Criticality in the Shipment of Special Nuclear Materials
1960		Part 31—Radiation Safety for Radiographic Operations (predecessor to Part 34); Part 140—Financial Protection Requirements and Indemnity Agreements (Price Anderson)
1961		Part 40—Domestic Licensing of Source Material
1962		Part 2—Rules of Practice; Part 150—Agreement States
1965		Part 30—Update to Licensing Byproduct Material; Part 31—General Licenses for Byproduct Material; Part 32—Domestic Licenses to Manufacture or Transfer Byproduct Material; Part 33—Broad Scope Licenses for Byproduct Material; Part 34—Radiation Safety for Radiography; Part 35—Medical Uses of Byproduct Material; Part 36—Licenses for Irradiators
1966		Part 71—Packaging of Radioactive Material for Transport
1969	National Environmental Policy Act	
1973		Part 19—Notices to Workers
1974	Beginning of radiotherapy overexposures because of miscalibration of ^{60}Co source at Riverside Methodist Hospital, Columbus, Ohio; Energy Reorganization Act of 1974	
1975	Establishment of the NRC (January)	
1978	Uranium Mill Tailings Radiation Control Act of 1978	Part 110—Export and Import of Nuclear Equipment and Material
1979	Accident at Three Mile Island Unit 2 (March)	
1980	^{90}Y overexposures during medical therapy, Houston, Texas; Low-Level Radioactive Waste Policy Act of 1980	
1981		Part 60—High Level Waste Repositories
1982	Nuclear Waste Policy Act of 1982	Part 61—Low Level Waste Disposal
1984		Part 51—Environmental Protection Regulations
1985	Low-Level Radioactive Waste Policy Amendments Act of 1985	Part 40—Update for Mill Tailings Regulations

1986	Accident at Chernobyl Unit 4 (April)	Part 171—Annual Fees
1987	Nuclear Waste Policy Amendments Act of 1987	Part 39—Licenses for Well Logging
1988		Part 72—Spent Fuel Storage
1989		Part 62—Emergency Access to Low Level Waste Disposal Facilities
1991		Part 20—Major update to Standards for Protection Against Radiation
1992	Energy Policy Act of 1992; Brachytherapy overexposure at Indiana Regional Cancer Center, Indiana, Pennsylvania (November)	
1993		Part 36—Update to Licenses for Irradiators
1994		Part 76—Certification of the Gaseous Diffusion Plants
1995		Part 71—Update for Transportation of Radioactive Material
1997		Part 34—Update to Radiography Licensing
2000		Part 31—Update to General Licenses for Byproduct Material; Part 70—Update for Licensing Fuel Cycle Facilities (Subpart H)
2001	Terrorist Attacks on US (September)	
2002		Part 35—Update to Medical Use of Byproduct Material
2005	Energy Policy Act of 2005	Part 110—Update to Export and Import to Incorporate Code of Conduct for Radiation Sources (Appendix P)
2013		Part 37—Security Requirements for Byproduct Material

Appendix B—Causes for Materials Program Resource Increases and Decreases

Fiscal Year	Causes for Resource INCREASE	Causes for Resource DECREASE	New Agreement States
2001	• Resource increase because of initiation of the orphan source program to address situations in which non-licensees find themselves in possession of radioactive sources they did not seek to possess	• Resource decrease because of Oklahoma becoming an Agreement State in September 2000 • Resource decrease because of improved efficiency of the licensing and inspection process	Oklahoma, September 2000
2002	• FTE increase to support the NRC's preparation for the transfer of approximately 1,150 materials licenses to new Agreement States (150 licenses to Minnesota in late FY 2002; 750 licenses to Pennsylvania and 250 licenses to Wisconsin in FY 2003), and to provide continuing oversight, coordination, and technical support to a growing number of Agreement States • Increased contract support, travel, and FTE resulting from the expansion of the NRC's risk assessment in the Nuclear Materials Safety arena consisting of development of probabilistic risk assessment tools and guidance to risk inform the materials regulations • Increase in contract support and travel to support increased internal training to enhance staff capability	• FTE decrease because of completion of 10 CFR Part 35 implementation activities in FY 2001 • Resource decrease because of anticipated efficiencies that result from streamlining the materials enforcement process	

2003	• Resource increase to develop a new, integrated information system—the Materials and Waste Integrated Support System—that will increase operational efficiency and replace older systems • Resource increase to support the NRC's preparation for transfer of 300–400 materials licenses to new Agreement States, and to provide continuing oversight, coordination, and technical support to a growing number of Agreement States • Resource increase to fund activity to convert the Fortran-based database on dose models to current operating systems, thus establishing in house capability for reviewing and revising these factors and limits in the future. • Resource increase in response to post-9-11 activities including the issuance of Orders to irradiators, M&Ds, etc. This required training of inspectors and resource-intensive reviews with HQ for all findings. Additional administrative requirements for the control of SGI-M materials were implemented and added complexity. These were additional inspections that needed to be conducted every 2 years. Few Agreement States agreed to conduct these inspections so it increased the number of required materials inspections.	FTE decrease in FY 2003 because of: • Completion of reviews for the new Agreement States, • licensing and inspection workload reductions associated with the transfer of 150 licenses to Minnesota, and 250 licenses to Wisconsin • Reductions in resources provided for general licensee follow-up efforts as the registration program matures • Process efficiencies • Decrease in legal support because of a decline in uranium recovery work	Wisconsin, August 2003
2004	• Resources increase to improve regulatory control of radioactive sources • GAO-03-804, "National Security: Federal and State Action Needed to Improve Security of Sealed Radioactive Sources" – Several recommendations – in particular, recommended the NRC modify process of issuing specific licenses to ensure that sealed sources cannot be purchased before NRC verification—through inspection or other means—that the materials will be used as intended.	• Resources decrease because of efficiencies in the materials inspection program and rulemaking and a reduced level of effort for licensing guidance. • Resources decrease to reflect Wisconsin becoming an Agreement State	
2005	• Resource increase for materials licensing, materials incident response, materials Agreement State activities, and maintenance and operation of, and improvement to, materials-related information management technologies • Increased resources for NARM licensing • Changes in sensitive unclassified non-safeguards information policy required additional administrative work in licensing and inspection • The NRC issued Increased Control Orders on 11/14/05 and 12/22/05. Licensees required implementation date—5/13/06. This caused expanded effort and complexity of our inspections	• Resource decrease because of decrease in rulemakings, technical training, and indirect staff	

2006	• Resources increase primarily to develop and implement a national registry of radioactive sources of concern • Resources increase to address materials incident response and security inspections; restore historic funding levels for the CRCPD; fund the triennial meeting with governor-appointed State Liaison Officers; fund maintenance and operation of, and improvement to materials related information management technologies such as LTS • Development and implementation of Enforcement Guidance Memorandum (EGM) 06-003 for discretion for Good Faith Effort required additional resources • Escalated Enforcement—Significant resource increase because of the number of enforcement cases related to Increased Controls (both using the EGM and those not meeting the EGM) • Pre-licensing visits were implemented—initial implementation 5/06 and final implementation 11/06	• Resources decrease because of Minnesota becoming an Agreement State	Minnesota, March 2006
2007	• 2007 GAO sting of the NRC licensing process resulted in immediate and long-term corrective actions to improve oversight of the licensing process	• Resources decrease because of implementation of a more risk-informed set of inspection priorities and inspection procedures • Resource decrease because of reduction in information technology costs associated with the near-completion of transition of the LTS to a Web-based system, as well as efficiencies gained in materials users licensing and inspection activities.	
2008	• Since the mid-2000s, there have been several new medical devices (35.1000); e.g., HDR, Beta Cath, Y-90, Gamma knife, which have added complexity to the associated licensing and inspection activities • Licensing resources increased for NARM • Resource increase for enhanced regulatory oversight for material licensing activities following the 2007 GAO sting, and subsequent recommendations from the GAO, the U.S. Senate Permanent Subcommittee on Investigations, and the Office of the Inspector General	• Resources decrease for homeland security activities including rulemakings, and for materials licensing reviews • Reduction in funding for WBL, and research support for human reliability issues and dose assessments • Resources continued to decrease in materials inspection program by implementing a more risk informed set of inspection priorities and inspection procedures, focusing those resources more precisely on the types of facilities and licensee activities that are most critical to maintaining safe operation	Pennsyl-vania, March 2008

2009	• Resources increase for pre-licensing site visits and development of pre-licensing guidance • Resource increase for development and implementation of a national registry of radioactive sources to improve the controls on radioactive materials through the NSTS and WBL • Resource increase will also support training for Agreement State personnel, and new licensing requirements mandated by the Energy Policy Act of 2005 to regulate NARM	• Regional resources decreased after PA became an Agreement State the previous year	Virginia, March 2009 New Jersey, September 2009
2010	• Resources increase to support the transfer of funding responsibility for tokens and credential costs for the WBL and NSTS systems • Resources increase to support the development of reliability analysis tools for byproduct materials, which will support risk informing the nuclear materials regulatory process • Resources increase to support increased enforcement and allegation workload as well as increased use of alternative dispute resolution • Increase in regional resources (Region I) to perform environmental assessments in support of Research and Test Reactors license renewals	• Regional resources decreased after VA and NJ became Agreement States the previous year	
2011	• Resources increased because of an increase in renewal applications and increases in legal advice for licensing hearings • Resources increase because of development of radiation protection regulations and guidance related to the 2007 recommendations of the International Commission on Radiation Protection • Resources increase because of extensive updates to licensing guidance series, NUREG-1556 • Changes in Part 30 required increased financial assurance which required additional staff effort in licensing and inspection to ensure compliance with new requirements	• No significant resource decreases	
2012	• Resource increase for rulemaking including high priority amendments to 10 CFR Parts 35 and 71 • Resource increase for research, event response and international activities • Resource increase for Homeland Security to support the NSTS, WBL, and LVS	• Resource decreases to licensing (new applications, amendments, renewals, and terminations) • Resource decreases to oversight (inspections, event evaluations, allegations, investigations, enforcement, etc.) • Resource decreases to the State, Tribal, and Federal Programs efforts • Decreased resources related to Research and Test Reactor license renewal support	

2013	• No significant resource increases	• No significant resource decreases	
2014	• Significantly increased effort on inspection of Category 1 and 2 licensees because of new Part 37	• Resources decreased in the Oversight, Rulemaking, and Generic Homeland Security Product Lines because of reductions in agency overhead, realignment of rulemaking resources, and reductions to IT and reclassification of generic homeland security resources within the budget structure	
2015	• No significant resource increases	• Resources decrease because of a reduction in agency overhead and the reclassification of generic homeland security resources within the budget structure	
2016	• No significant resource increases	• No significant resource decreases	
2017	• No significant resource increases	• Resources decrease due to Project Aim re-baselining	

* Exact resource increases and decreases that resulted from the causes were not identified because of the limited detail provided in historical documents.