

NUCLEAR MATERIALS SAFETY CHAPTER

The Nuclear Materials Safety arena encompasses regulatory activities associated with nuclear fuel cycle facilities and nuclear materials users. It includes 10 major fuel cycle facilities and several other smaller licensed facilities, and more than 20,000 specific materials licensees regulated either by NRC or by Agreement States. In addition, there are estimated to be 100,000 general licensees within the arena. This diverse regulated community includes: uranium conversion; uranium enrichment; nuclear fuel fabrication; fuel research and pilot facilities; and large and small users of nuclear material for industrial, medical, or academic purposes. The latter group includes: radiographers, hospitals, private physicians, nuclear gauge users, large and small universities, and others.

Nuclear Materials Arena Statutory Authority
<ul style="list-style-type: none">- Atomic Energy Act of 1954, as amended- Energy Reorganization Act of 1974, as amended- Energy Policy Act of 1992- Clean Air Act of 1977, as amended- National Environmental Policy Act- Nuclear Non-Proliferation Act of 1978- Convention for the Physical Protection of Nuclear Material

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STRATEGIC GOAL: Prevent radiation-related deaths and illnesses¹ and protect the environment in the use of source, byproduct, and special nuclear material² for medical, academic, and industrial purposes and safeguard special nuclear material and facilities.

This strategic goal represents the principal focus of the Nuclear Materials Safety arena. The goal is to achieve our mission and fulfill our statutory requirements as stated above. For fuel cycle activities, NRC is the primary regulatory body. For materials activities, NRC currently shares its regulatory authority with 31 Agreement States throughout the country. Throughout the arena, it is recognized that licensees³, and other stakeholders are key participants in the collective efforts that will be necessary to achieve program success. The following measures will indicate whether this strategic goal is being achieved.

MEASURES	METRIC
1. Number of deaths resulting from civilian uses of source, byproduct, or special nuclear materials, or from other hazardous materials used or produced from license material.	Zero
2. Number of significant radiation or hazardous material exposures ⁴ resulting from the loss or use of source, byproduct, and special nuclear materials.	TBD

¹ Illnesses are defined as permanent health effects.

² For fuel cycle activities, this extends to other hazardous materials used with, or produced from licensed material, consistent with proposed amendments to 10 CFR Part 70.

³ “Licensees” as used in this Strategic Plan include persons required to be licensed (as defined in Section 11s of the Atomic Energy Act, as amended) as well as, where appropriate, applicants for licenses, certificate of compliance holders and applicants for certificates of compliance, contractors (including subcontractors, suppliers, consultants, and vendors), and all persons subject to NRC’s regulatory jurisdiction.

⁴ Significant exposures are defined as those that result in unintended permanent functional damage to an organ or a physiological system as determined by a physician. Hazardous material exposures only apply to fuel cycle activities as referenced in footnote 2, above.

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3. Number of releases of radioactive material that cause an adverse impact on the environment. ⁵	Zero
4. Number of losses, thefts, or diversion of formula quantities of strategic special nuclear material, or radiological sabotages or unauthorized enrichment of special nuclear material regulated by the NRC. ⁶	Zero
5. Number of unauthorized disclosures or compromises of classified information which cause damage to national security. ⁷	Zero

These measures identify events that would result in significant adverse impacts on public health and safety, the national security, or the environment. They relate to events associated with regulated activities that must be accurately reported by licensees to the NRC and Agreement States in accordance with NRC regulations. These could result from NRC licensee fuel cycle safety and safeguards program activities, or from activities of NRC or Agreement State licensees related to the use of nuclear materials for medical, academic, or industrial purposes. Except for measure 2, any occurrence related to the zero value metrics may be considered a failure to achieve the strategic goal for this arena. With respect to measure 2, NRC believes there have been a small number of such occurrences over the past few years. We are working to develop an accurate estimate. Sometimes this is difficult to quantify since some events require medical estimates of the probability of functional damage to an organ developing at a later date.

⁵ Releases that have the potential to cause “adverse impact” are currently undefined. As a surrogate, we will use those that exceed the limits for reporting abnormal occurrences as given by AO criteria 1.B.1 {normally 5,000 times Table 2 (air and water) of Appendix B, Part 20}.

⁶ In accordance with Appendix G to 10 CFR 73. I(a)(1) and (2), and 10 CFR 74.11(a).

⁷ In accordance with the requirements of 10 CFR 95.57.

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Performance Goal: Maintain safety and safeguards.

NRC will continue to protect the public, workers and the environment, and ensure that licensed and authorized activities will not be inimical to the common defense and security. This will be accomplished by ensuring that regulated materials⁸ arena activities are undertaken consistent with applicable statutes and regulations. In so doing, NRC will continue to provide reasonable assurance that adverse impacts will be prevented from licensees' use of byproduct, source, and special nuclear material. This also entails maintaining a high assurance against loss, theft, diversion, or unauthorized enrichment of nuclear material; sabotage of nuclear facilities; and protection of classified matter to protect the common defense and security.

This is the NRC's primary performance goal, which has a higher priority than the other performance goals. In working toward this goal, we will apply the NRC's principles of good regulation. Principles related to independence, openness, regulatory clarity, and reliability are applicable to this goal.

Although the goal is to maintain, rather than increase safety and safeguards, this represents a composite approach for the many categories of licensees represented in this arena. Because of the diversity within and among licensed activities in this arena, and the risks involved in the activities, additional safety improvements in certain areas may be warranted. Most nuclear material facilities and a large majority of materials licensees have operated safely and securely for many years. The industries, the NRC, and the Agreement States (who share this regulatory responsibility for over 15,000 materials licensees), have recognized that certain elements of the fuel cycle and materials industries are mature and practices and standards already in place have been tested over time and found to be acceptable in maintaining safety and security. On the other hand, other elements of this arena involve newer technologies and practices. In both cases, regulators must pursue risk-informed and performance-based approaches, where justified, to focus our attention on those areas of highest safety and security priority.

The arena also recognizes NRC's shared regulatory responsibility with 31 Agreement States. The adequacy and compatibility of these State programs, compared with NRC's own regulatory programs are important to assure that a uniform nuclear safety policy exists throughout the nation. This uniformity will take on increased significance as more States assume regulatory authority in this arena over the next several years. In recognition of the important contributions of the

⁸ For fuel cycle activities, this also extends to other hazardous materials used with, or produced from licensed material, consistent with proposed amendments to 10 CFR Part 70.

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Agreement States to maintaining safety, NRC will encourage States to pursue a more active role in the implementation of strategies that contribute to the safety performance goal. The NRC and Agreement States will take decisive action to improve the safety performance of licensees identified as falling below acceptable levels to ensure public health and protection from undue hazards.

Finally, this goal recognizes NRC's mandate to protect the common defense and security. NRC's safeguards, physical protection, and threat assessment activities all combine to provide high assurance that commercial activities involving special nuclear material (SNM) are not inimical to this purpose and do not constitute an unreasonable risk to public health and safety. NRC's threat assessment function contributes to national and international programs designed to identify and limit the risk of proliferation of weapons of mass destruction and weapons-usable materials and threats posed by terrorists, criminals, and foreign regimes determined to commit hostile acts against NRC regulated facilities and activities. Our safeguards system monitors and ensures NRC licensees maintain nuclear material protection, control, and accountability, and our physical protection component represents the principal barrier for those who would attempt to sabotage, steal or divert SNM. Such an important function has continued to be an effective deterrent against these threats, but our activities will take on increased priority as the availability of weapons-usable material and the information technology to build nuclear explosives continues to become more widespread, and the ever-increasing vulnerabilities to cyber-terrorism continue as systems become more and more automated.

Strategies

- *We will continue to improve the regulatory framework to increase our focus on safety and safeguards.*

In the Materials Arena programs, the regulatory framework continues to evolve, even though many parts of the fuel cycle and nuclear materials industries are in a mature state. The regulations contain some prescriptive requirements, where necessary, while other sections of the regulations are more performance-based. As appropriate for the individual Materials Arena programs, risk-informed and performance-based approaches will be incorporated incrementally to improve the focus on safety of the regulations, and related guidance making up the regulatory framework. We will ensure, by using risk assessment techniques for differentiating between high- and low-risk activities, that our regulatory focus is on those activities that pose the greatest risk to the public. We will focus on those areas where important gaps in information exist and where uncertainties exist about the significance to risk. We will develop guidance to ensure that specific applications of risk

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assessment methods are suitable and that there is consistency in their use in our decision-making process. It should be noted that due to the diversity of programs within the Materials Safety Arena, risk assessment techniques will only be used where the subject matter is amenable to the risk assessment strategy and where the greatest benefit could be derived.

For programs where new technology is involved or where regulations or guidance are new or evolving, interactions with applicants will be important to discuss acceptable ways to comply with the regulatory requirements. More prescriptive requirements may be appropriate for new technologies.

Finally, we will evaluate potential new information from research, new safety issues, changing external factors, and licensee operational experience so that improvements can be made to maintain an adequate regulatory framework. In this regard, we will be quick to share relevant generic safety information (e.g. Bulletins, Information Notices) with Agreement States, and other licensees, in order that we can learn from each other's experiences. Related guidance will be updated periodically, and will take into account risk information, whenever possible, and allow flexibility for licensees to develop performance-based solutions, when these solutions are shown to be acceptable from a safety perspective.

- *We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework.*

In the Materials arena, NRC issues several hundred new licenses each year and terminates about the same number. NRC approves over 3,000 amendment requests and makes decisions on license renewals as the licenses approach their expiration dates. Some of these actions are fairly routine in nature, and these decisions can be reached in a relatively short period of time. Conversely, some major materials licensees, including the fuel facilities, engage in more complex operations. Therefore, the decisions associated with these licenses require a more rigorous review of licensee personnel qualifications, safety and safeguards programs, systems, and facilities. On some occasions, these evaluations include safety, safeguards, or environmental reviews; issue resolution; and documentation of the technical bases and findings in publicly-available safety and safeguards evaluation reports and either environmental assessments or environmental impact statements. Licensing submittals and approvals are often made easier when licensees and reviewers use available guidance documents. These documents are not intended to supplant the regulatory requirements. They are intended to serve as tools to assist licensees, and license reviewers in their understanding of the license application and review process. Therefore,

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they will be updated on regular intervals to maintain currency. The regulations will be applied to independently evaluate the licensees' demonstrations that the proposed activities comply with the regulations. While conducting these evaluations, we will employ risk-informed methods and data, where appropriate. In addition, the adjudicatory hearing process will support final licensing decisions. Technical assistance will be provided to the Agreement States, when requested, in conducting their reviews.

- *We will confirm that licensees understand and carry out their primary responsibility for conducting activities consistent with the regulatory framework.*

For fuel cycle and materials licensees, investigations, inspections or other independent approaches (e.g., third party reviews) will continue to be important methods to verify that licensees understand their responsibility to safety and that their activities remain in compliance with the regulatory requirements. Inspections must identify any safety and safeguards issues and resolve them before they affect safe and secure operations. We will use the risk-informed regulatory framework to inspect licensees at varying frequencies and with varying techniques, depending on the relative risks of the activities. Increased attention will be given to licensees with marginal performance, by focusing inspection resources on the basis of licensee performance. Allegations regarding licensee performance will be appropriately and objectively addressed in a timely manner. Allegations of potential wrongdoing will be appropriately and objectively investigated in a timely manner. Enforcement sanctions for violations of regulatory requirements will be used if appropriate.

- *We will respond to operational events involving potential radiological, national defense, or security consequences.*

We contribute to maintaining safety and safeguards: by providing timely, accurate, and complete assessments of events; by evaluating recommendations of the licensees for actions to protect the public or national defense and security; by distributing generic lessons learned from operational events; and by coordinating with other federal agencies, state and local governments, and the licensee. The technical staff will have sufficient skills and knowledge to support the agency or State in responding to operational events. Additional support will be provided by the continuously-staffed Incident Response Operations Center. Periodic exercises will be conducted to ensure response organizations are proficient and experienced staff are trained to respond to operational events according to their safety or safeguards significance. Incident investigation capabilities also will be maintained.

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- *We will continue to evolve, along with Agreement States materials programs, into a single “National Materials Program”, by encouraging the States to continue to pursue a more active role in the regulatory process.*

Safety is a shared responsibility between NRC, the Agreement States, and our licensees. A total of 31 States regulate over 15,000 specific radioactive materials licenses, as compared to 5,300 regulated by NRC. Several other States continue to work toward becoming Agreement States in the next few years. This trend will continue to shift more of the regulatory responsibility from NRC to States, and will require more cooperation and coordination between NRC and the States to assure safe licensee activities throughout the country. Development of a national strategy and infrastructure for regulating materials licenses in this new environment, will help assure a more consistent and effective national focus on safe licensee performance for all of the 20,000 materials licensees throughout the country.

We will continue to conduct Integrated Materials Performance Evaluation Program (IMPEP) reviews to verify the adequacy and compatibility of Agreement State materials programs and the technical quality and consistency of NRC’s materials program licensing and inspection activities. The process is also designed to identify performance strengths and weaknesses.

Over the last several years, increased cooperation between NRC and the Agreement States has helped identify solutions to common program issues. NRC will encourage the States to continue to take on a larger share of program responsibilities in the future.

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MEASURES	METRIC (subject to further validation)
1. Number of losses of licensed material as reported to Congress annually. ⁹	≤ 300 per year nationally. 272 nationally in FY 1998, 188 nationally in FY 1999.
2. Number of occurrences of accidental criticality.	Zero.
3. Number of overexposures ¹⁰ that exceed applicable regulatory limits/standards.	≤ 20 per year nationally. (has ranged from 10-18 over last 4 years).
4. Number of misadministrations ¹¹ .	≤ 45 per year nationally. (has ranged from 33-46 over last 4 years).
5. Number of releases of radioactive material from operating facilities that exceeds the regulatory limits. ¹²	≤ 40 year nationally. (has ranged from 17-36 over last 4 years).
6. Number of substantiated cases of attempted malevolent use of source, byproduct, or special nuclear material.	≤ 5 per year nationally.

⁹ Material entering the public domain in an uncontrolled manner. Includes losses or thefts of controlled material that are listed in Appendix C of abnormal occurrence report to Congress. Not all of these are safety-significant events. Some are included because they caused NRC to increase attention or oversight of a program area, or because they received significant media coverage.

¹⁰ Overexposures are those that exceed limits as provided by 10 CFR 20.2203(a)(2) and (3). For fuel cycle activities, this extends to other hazardous materials used with, or produced from licensed material, consistent with proposed amendments to 10 CFR 70. Reportable chemical exposures are those that exceed license commitments.

¹¹ Misadministrations reported under 10 CFR 35.

¹² Releases for which a 24 hour notification is required under 10 CFR 20.2202(b)(2) and 30 day reporting requirement under 10.CFR 20.2203(a)(3).

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7. Number of substantiated breakdowns of physical protection or material control and accounting systems that results in a vulnerability to radiological sabotage, theft, diversion or unauthorized enrichment of special nuclear material. ¹³	Zero
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Maintaining nuclear materials safety and safeguards, is the primary goal for the various activities in the Nuclear Materials Arena. The metrics for these measures would maintain safety performance at about the same level as the prior years. The measures in the performance goal represent a more conservative threshold for measuring NRC and Agreement State performance to preclude violating the strategic goal measures. Except for measures 2 and 7, all of the other safety measures will include data from NRC and Agreement State activities.

This arena involves a range of activities that, during the course of normal day-to-day operations, place radioactive material in medical or industrial settings that provide more opportunities than other arenas for overexposures, misadministrations, and/or releases to occur. In the medical field alone, several million procedures take place each year that involve radioactive material used to diagnose or treat diseases. While the NRC and Agreement States continue to support a regulatory philosophy that places safety as the pre-eminent consideration, this plan acknowledges that the above numbers represent the most realistic set of metrics, based on our available performance data. The metrics include some events of limited safety significance, such as a number of lost portable moisture density gauges, tracked under measure 1, even though few such events have resulted in overexposures. These events are included, since they could be indicators of potential weaknesses that could later result in a failure to achieve the strategic goals in this arena. Collectively, the measures were chosen to identify events where NRC and/or Agreement States can monitor their success to assure that there is no statistically-significant increase in the number of events that could result in public or worker overexposures, releases to the environment, or vulnerabilities to radiological sabotage, theft, or diversion.

¹³ We recognize that no explicit reporting requirements exist for substantiated breakdown determinations. NRC relies on its safeguards inspection findings and licensee notifications.

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Performance Goal: Increase Public Confidence.

NRC views public confidence as an important performance goal for the Agency. NRC desires that diverse stakeholder groups increasingly recognize that NRC and Agreement States actions assure that the public health and safety, the common defense and security, and the environment are, and will remain, adequately protected from hazards resulting from the use of radioactive materials. In order to reach this goal, we must be viewed as independent, open, clear, and reliable regulators dedicated to protecting the public's health and safety, common defense and security, and the environment.

For this performance goal, the public means a diverse group of stakeholders who are affected by, or who affect, the regulatory programs in this arena. Stakeholders include: Congress, NRC and Agreement State licensees, other Federal agencies, States, Indian tribes, local governments, industry, the industry workers, the international community, citizen groups, and rate payers.

The NRC must forthrightly inform the public about nuclear safety and safeguards incidents and issues and provide avenues for meaningful input and dialogue. However, issues involving nuclear security or related to national defense may not always be able to be discussed in a public forum. Because of the diversity of stakeholder and public interests within this arena, the goal recognizes that there may not always be a consensus. This goal also recognizes that, although the public may not always agree with NRC's actions, public confidence in NRC is enhanced when the Agency listens to all interested parties and makes its decisions in a thorough, disciplined, and timely manner.

Although NRC has conducted its regulatory oversight openly and has provided information to a variety of stakeholders, it recognizes the need for continued improvement, especially with respect to future regulatory changes and interactions with Agreement States. This means that continued dialogue between NRC and the Agreement States is required to develop solutions to common problems that are compatible within each other's regulatory framework. NRC recently completed a variety of initiatives to better inform stakeholders and obtain their input on significant issues. Based on the initial efforts, our goal is to expand efforts and achieve greater improvement in this area. This may include more public meetings and more workshops with important sectors of the regulated community. NRC will increase its efforts for public outreach to effectively communicate with and involve the diverse stakeholders early in regulatory activities.

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Strategies

- *We will expand stakeholders access to the NRC. We will listen to their concerns and provide more opportunities for them to be more fully involved in the regulatory process.*

One of the attributes of strong and fair regulation in the materials arena involves consistent and early public involvement. The agency recognizes the public interest and concern in the proper regulation of materials arena activities. The agency further recognizes its responsibility to provide opportunities for meaningful public interaction and involvement. NRC will listen to, and be responsive to, requests, inquiries, and concerns from the public. We will provide opportunities for the stakeholders to bring information and issues to NRC by holding open meetings in the vicinity of those affected, providing adequate notice of meetings, developing and implementing communications plans for major regulatory activities, and holding workshops. We will consistently consider this input in planning changes and making decisions relating to our practices, rules, and processes.

- *We will communicate more clearly. We will add more focus, clarity, and consistency to our message and present information in the proper context with respect to the risk of the activity.*

Public confidence in the NRC will be enhanced by avoiding unnecessarily raising stakeholder concerns. We can avoid concerns if the information is presented in a manner that is easily understood and placed in its proper safety context. Whenever possible, we will use quick, personalized forms of contact with our stakeholders. Our communications with the public will be designed to foster greater understanding of, and confidence in, our regulatory program. The information we disseminate will be clear, technically sound, accurate, reliable, objective, and timely. We will take full advantage of the Internet and new technology for information dissemination. We will protect the privacy, proprietary, and classified nature of information. All stakeholders should be able to rely on our statements and information as being objective and not promotional. NRC will clearly communicate to and educate stakeholders about its precise role in the materials arena.

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- *We will enhance NRC's accountability and credibility. We will assure that NRC's activities are consistent with its mission.*

The public's confidence in nuclear materials arena activities is influenced by its perception of NRC. It has been recommended that we should benchmark that confidence using a public survey instrument. The NRC is assessing the feasibility of such a survey. We will candidly acknowledge our mistakes and our failures to meet our commitments. Finally, as part of implementing a Planning, Budgeting, and Program Management (PBPM) process, we will prepare a strategic plan that provides visibility to our goals and performance measures. We will manage to that performance and will measure and report on achieving performance goals as they relate to public health and safety and safeguards.

Public confidence is also influenced by information about licensee performance. We will collect information about licensee performance in the nuclear materials safety arena and report that information objectively to the public. Where licensee performance is outside established criteria, corrective action will be taken and communicated to the public. Where safety, security, or environmental issues are raised, NRC will communicate to the public how these issues are being addressed.

- *We will increase efforts to share program success information with the public.*

We will explore additional opportunities to convey our actions and activities, including achievements, to a broader audience. This may include: expanding our reports to Congress, increasing our information exchange with the media outlets, and enhancing our external and internal home pages.

- *We will foster an environment where safety and security issues can be openly identified without fear of retribution.*

Public confidence is enhanced in an environment where safety and security issues can be raised and addressed without fear of retribution. Examples of how this strategy will be implemented in this arena include: conducting NRC's 10 CFR 2.206 petition process, responding to allegations, addressing safety-conscious work environment concerns, and implementing NRC's programs for differing professional views/opinions. We will also participate in the agency's pilot program to solicit feedback from individuals raising safety or security issues to assess the effectiveness of NRC's handling of allegations. Finally, we will encourage licensees and applicants to be open and responsive to the public affected by their regulated actions.

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Measure (examples for discussion, see below).	Metric
1. Percentage of improvement in public confidence that the public is safe now and in the future.	TBD (Increase)
2. Percentage of improvement in public confidence that the environment is protected now and in the future.	TBD (Increase)
3. Percentage of improvement in public confidence that the common defense and security is maintained.	TBD (Increase)
4. Percentage of improvement in public confidence that the NRC is an independent, open, clear and reliable, and efficient regulator.	TBD (Increase)

Measures are needed to evaluate whether we have achieved our performance goal of increased public confidence. Stakeholders have recommended that the NRC needs to benchmark its *Public Confidence* Goal using a public survey instrument. We are assessing the feasibility of such a survey. The above measures will be replaced by actual measures, after decisions are made whether to carry out the survey, how to conduct it, and how to interpret the initial results. We will provide revisions to the Strategic Plan when the actual measures and metrics are available. During the interim, we will identify and report our efforts to increase public confidence in our annual performance plan and performance report.

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Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

NRC will continue to seek improvements in its regulatory processes to become more effective, efficient, and realistic. NRC will identify and focus on necessary and sufficient regulatory activities that are linked to its goals. In those regulatory activities, NRC will strive to optimize regulatory programs and processes, where possible, while assuring safety and security, and improving public confidence. In working toward this goal, NRC will apply its principles of good regulation; for example, efficiency, clarity, and reliability are most closely applicable to this goal.

NRC will ensure its decisions are scientifically-based, risk-informed, and shaped by operational experience, new information, and research. As a result, NRC's decisions will be realistic, systematic, and appropriately treat areas of uncertainty. NRC will ensure its procedures, processes, and expectations are better-defined, clearer, and more transparent. NRC's regulatory actions will support more consistent, reliable, predictable, and timely decision-making. Furthermore, NRC will seek to minimize duplication of efforts with stakeholders to achieve this goal, while relying on the technical and managerial competence of its staff to achieve success.

By striving to become more effective, efficient, and realistic while continuing to assure adequate protection of the public health and safety and the common defense and security, NRC intends to keep regulatory burden and related costs to licensees and applicants as low as practical. NRC will capitalize on advances in technology and implement changes to improve internal processes related to regulatory actions. As part of this effort, NRC will continue its efforts to develop and update licensing and inspection guidance in order to improve the consistent, effective, and efficient implementation of its policies in the field. Furthermore, NRC will strive to be less prescriptive and will apply risk-informed, performance-based approaches where it is appropriate to do so.

Effectiveness means producing the necessary and sufficient work to achieve our goals. NRC must periodically challenge the value of NRC programs and activities based on how they contribute to the achievement of goals. NRC business processes and regulatory decisions will reflect high standards of quality and be technically sound. Specific challenges in this regard involve: (1) risk-informing NRC's regulatory programs; (2) preparing to address evolving technologies and a changing regulatory environment; and, (3) improving the predictability and consistency of agency decisions .

Efficiency means conducting our work productively and on time. Efficiency will be enhanced by simplifying or streamlining our internal processes based on self-assessment and experience, using improved tools, and becoming more timely and predictable in delivery of services and decisions.

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In order to become more effective and efficient, NRC will plan and schedule its work activities and identify key milestones to monitor progress. When issues emerge, NRC will readjust plans, schedules, and resource allocations, if necessary, to ensure attention is focused on the highest priority activities and conducted efficiently. NRC decisions will be made more realistic by eliminating excessive conservatism. Realism is supported by risk information, research results, and operational experience.

Strategies

- *We will continue to improve the regulatory framework to increase our effectiveness, efficiency and realism.*

We will make improvements to our regulatory framework or take other agency actions (e.g., seek legislative changes) to resolve circumstances that reduce our effectiveness or efficiency. For example, improvements would be needed for circumstances such as: 1) overlapping regulatory responsibility or dual regulation, 2) conflicting positions regarding regulatory jurisdiction, and 3) conflicting standards that impact finality of licensing decisions. Furthermore, we will incorporate risk-informed and performance-based approaches, as appropriate, into our regulatory framework where they can substantially improve our effectiveness, efficiency, and realism (i.e., reduce excessive conservatism). This will be accomplished, in part, by conducting an integrated evaluation of risk information, inspection findings, operating experience, research results, and cost data as part of the agency-wide Probabilistic Risk Assessment Implementation Plan. In addition, we will continue to incorporate, where applicable, existing consensus standards into our regulatory framework. We will also encourage stakeholders to develop and use new consensus standards.

Furthermore, we will develop and revise appropriate licensing and inspection guidance so that applicants and staff have a clear and consistent understanding to develop and review licensing applications, respectively. This guidance should minimize the staff's requests for additional information, subsequent license revisions, and additional rounds of staff review. It will also help the staff prepare for, and conduct, inspections.

Finally, we will anticipate, through research and technical studies, opportunities for regulatory improvements that may come from industry's introduction of new technologies. Similarly, we will use research, technical studies, and risk information to reduce unnecessary conservatism, and ensure that the regulatory framework is based on technically-sound, and realistic information.

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- *We will prioritize our work, then plan and schedule activities accordingly to achieve desired outcomes.*

We will fully implement a disciplined, integrated planning framework - the Planning, Budgeting, and Performance Management process and will transition to a more outcome-focused organization. Through this process, our programs and activities will be chosen and prioritized based on the significance of the work to the achievement of our performance goals. The chosen programs will be planned, scheduled, managed, monitored, and assessed through this process. When issues emerge, we will readjust our plans, schedules, and resource allocations, if necessary, to ensure attention is focused on the highest priority activities and conducted efficiently.

- *We will identify, prioritize and modify processes that allow for the most leveraged improvement.*

We will continually improve and standardize our processes through a robust program of self-assessment and application of lessons learned. In particular, effectiveness reviews of program and program support areas will be conducted to determine what work needs to be added, maintained, reduced, or eliminated in order to deliver the desired outcomes. Efficiency reviews of key processes in program and program support areas will be conducted to determine the most efficient means of delivering the desired outcomes.

- *We will improve decision-making in the implementation of our programs by increasing the authority for NRC management and staff and by holding them more accountable for results.*

We will improve decision-making across the implementation of all of our programs by a variety of approaches. First, we will develop a plan and infrastructure to provide a greater degree of staff empowerment. Staff will be empowered and accountable to take appropriate and necessary regulatory action and make regulatory decisions that are within the scope of the assigned position's responsibilities. We will develop a process to determine the appropriate level of regulatory decision-making for specific types of decisions consistent with our statutory and regulatory authority. This should streamline and simplify the technical and management review and approval process, including the elimination of certain reviews. We will increase the authority of the general staff and will work to establish a supportive environment that is based on individual empowerment, collegial assistance, and management trust. We will train management and staff on approaches to enhance quality and team building and improve collegial interaction.

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We will also enhance the technical competence of our staff to ensure an effective and efficient workforce. Particular attention will be given to recruiting, training, and retaining those specialized skills needed to conduct materials arena activities (e.g., health physics, criticality safety, threat assessment). Furthermore, we will ensure that the staff's decisions are supported by high quality and realistic information. We will actively pursue opportunities to leverage information technology to achieve the efficiency and effectiveness goal. Finally, the technical bases for decisions will be enhanced, where appropriate, by providing analytical tools to independently analyze information and licensee assessments.

- *We will continue to evolve, along with Agreement States materials programs, into a single "National Materials Program", by encouraging the States to continue to pursue a more active role in the regulatory process.*

Development of a more national strategy and infrastructure for regulating materials licenses consistently will take on increased emphasis and will ultimately make all parties more efficient and effective regulators, as several other States continue to work toward becoming Agreement States in the next few years.

NRC Headquarters has traditionally led the activities that established and improved the regulatory framework, while NRC's regions and Agreement States implemented the programs within this common framework. Over the last several years, increased cooperation between NRC and the Agreement States has helped identify solutions to common program issues. NRC will encourage the States to continue to take on a larger share of program responsibilities in the future. Examples include: Agreement State participation in NRC/Agreement State working groups, Agreement State participation in IMPEP and in the Nuclear Materials Events Database, and the assumption of responsibility by the Organization of Agreement States for planning and hosting the annual All Agreement States meeting. This increased interaction will allow NRC to gain additional insights from the comments and input of Agreement States, individually and collectively, especially when substantive program changes are being considered. The periodic IMPEP lessons learned and good practices reports provide examples so that one regulator can upgrade the effectiveness and efficiency of its program based on findings about another regulator. By expanding the States' participation in various Work Groups, NRC and Agreement States can avoid duplication of effort. These interactions will sharpen NRC and the Agreement States simultaneously. Collectively, these activities reflect an evolution toward a more unified and cohesive national program.

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Measure	Metric
1. Number of key process improvements achieved in selected program and support areas which increase efficiency, effectiveness, and realism.	2 process improvements per year
2. Percentage of NRC licensing actions, inspections, rulemaking and guidance products that are completed on time.	At least 80%.
3. Number of program deficiencies identified by internal or external sources (e.g., requests for rulemaking, 10 CFR 2.206 petitions, operational experience) where potential significant safety, environmental, or safeguards impacts were not adequately considered, or where significant operational impacts occur.	Less than or equal to two per year
4. Number of processes in which decision-making authority is reduced by at least one level.	2 reductions per year.

These measures and metrics are not applicable to Agreement States, since it is not within NRC's purview to evaluate States' efficiency, effectiveness, or realism, except when the activities are needed to demonstrate program adequacy and compatibility. Together, these measures were chosen to identify the conditions under which NRC would make continuous progress to assure that: its regulatory processes (i.e., rulemaking, licensing, inspections, and enforcement) are executed in a timely and business-like fashion; and its decisions are technically-sound and based on realistic information.

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PERFORMANCE GOAL: Reduce unnecessary regulatory burden on stakeholders.

NRC will strive to reduce unnecessary regulatory burden and associated public costs where possible, while achieving the other three performance goals. Unnecessary regulatory burden for NRC licensees may be defined as a set of regulatory licensing information and analysis requirements that goes beyond what is necessary and sufficient for providing reasonable assurance that public health and safety, the environment, and the common defense and security will be protected. The costs associated with NRC activities can impact a variety of NRC stakeholders. For some stakeholders, such as States and the public, costs could potentially result from actions by States to augment the NRC regulatory program, cleanup sites, or dispose of radioactive material using public funds. For others, such as applicants and licensees (and ultimately the public), unnecessary burden may be imposed by inappropriate technical review which could result in increased fees.

Although regulation, by its nature, is a burden, NRC will ensure that only the level of burden necessary to maintain safety is imposed on licensees. This can be achieved by using risk-informed and performance-based approaches, where justified, to focus attention on those areas of highest safety priority and by making more realistic decisions with no undue conservatism.

Consideration will be given to making regulatory burden commensurate with the risk of the regulated activity. Furthermore, regulatory burden associated with a safety enhancement will be considered in light of a cost benefit analysis prior to the imposition of a new regulatory requirement. Regulatory oversight will be fair, consistent, effective, and timely in its application. Costs associated with the regulatory infrastructure must be fair, equitable, and shared by all users.

NRC believes that, some of the regulatory burden in the Nuclear Materials arena associated with the regulations and practices in place over the years was not commensurate with the safety benefit. During these years, an ever-increasing body of technical knowledge, operational experience, and risk assessment tools has been accumulated. Within this arena, a risk review study is being conducted. Also, a risk review group has recently been established to implement a more risk-informed regulatory framework for these programs. These efforts are expected to provide the bases for reducing unnecessary regulatory burden in some areas, but perhaps increasing burden in others.

Strategies

- *We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.*

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We will use risk-informed and performance-based approaches, where appropriate, to ensure that all elements of our regulatory programs (i.e., regulations, guidance, licensing, assessment, inspection, and enforcement) are conducted commensurate with the level of risk. This will provide licensees with flexibility in meeting regulatory requirements. The scope and priority of changes in our regulatory processes will consider stakeholder input, the effects of dual regulation with other federal and state entities, and the cumulative effect each has on agency and licensee burden reduction. In addition, we will use research and technical studies to evaluate new information in order to identify areas in our regulatory programs where unnecessary burden can be reduced. New information includes: improvements in knowledge, advances in technology, and insights gained from operational and regulatory experience both domestically and internationally. Research will focus on identifying where unnecessary conservatism can be eliminated or reduced.

- *We will execute our programs and processes, consistent with the improved regulatory framework, in ways that impose no unnecessary costs to our stakeholders.*

As we execute our programs, we will make improvements to those aspects of our regulatory processes that had resulted in unnecessary costs to our stakeholders. In particular, we will evaluate the timeliness of actions and the necessity for multiple rounds of requests for additional information. As we make licensing decisions, conduct inspections, and take enforcement actions, we will take into account the necessity of any additional burdens imposed on licensees and other stakeholders.

- *We will actively seek stakeholder input to identify opportunities for reducing unnecessary regulatory burden.*

We will encourage licensees to identify for NRC consideration concerns with NRC's regulatory programs, such as untimely, inadequate, or inappropriate staff actions, that have resulted in unnecessary cost. In addition, we will continue initiatives to interact with stakeholders to ensure a mutual understanding of existing regulatory requirements, guidance or licensing decisions. Such interactions will provide opportunities for stakeholders to identify problems or suggest improvements. NRC will also be able to clarify or explain the basis for requirements, guidance, or licensing decisions, and why we believe they are necessary and sufficient. Where guidance is being developed or used for the first time, we will invite stakeholder feedback to identify aspects of the guidance that might be unclear, unnecessary, inflexible, or otherwise considered excessively burdensome by the licensee. Where licensees are using new requirements or guidance for the first time to prepare specific submittals, we will be available to interact with them upon request during the development of the submittals to resolve implementation questions or technical issues they identify that might help them prepare an acceptable submittal.

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Measure	Metric
1. Number of valid concerns where NRC regulatory activities have resulted in unnecessary burden to licensees.	TBD (% decrease)
2. Number of valid concerns where NRC regulatory activities have resulted in unnecessary burden to non-licensee stakeholders.	TBD
3. Percentage change in paperwork and recordkeeping imposed by NRC on its licensees.	25% hourly reduction within 5 years.

NRC wants its regulatory programs to be protective at reasonable cost and without undue conservatism. Furthermore, NRC will strive to optimize the burden imposed on applicants and licensees commensurate with the risk of the regulated activity. These performance goal measures are designed to assess how the agency is meeting this objective. For the first two measures, the staff would evaluate the validity of written licensee and other stakeholder complaints that NRC's staff action has resulted in unnecessary burden. For example, unnecessary burdens might result from staff action that is untimely, inappropriate, incomplete, inconsistent, unclear, or unduly conservative. The third measure recognizes the specific burden in terms of time and money represented by excessive paperwork and recordkeeping requirements.

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MAJOR EXTERNAL FACTORS AFFECTING THE NUCLEAR MATERIALS SAFETY ARENA

Listed below are assumptions about major external factors and how they might affect achieving the goals of our nuclear materials safety arena.

- One important external factor is whether or not NRC takes on the regulatory oversight responsibility of DOE facilities. Currently, NRC provides regulatory assistance to DOE under a Memorandum of Understanding (MOU) for the Hanford Tank Waste Remediation System privatization that may be transitioned to NRC regulation. Although this MOU allows NRC to advise DOE on the appropriate regulatory framework necessary for the rigors of commercial licensing expectations, DOE is not obligated to adopt any of our recommendations.

Thus, an early transition to NRC would require a phased and graded implementation strategy or possibly a reassessment of measures and strategies. NRC also participated jointly with DOE and OSHA to conduct pilot programs on the feasibility of external regulation of DOE facilities. Although no significant issues were found during the pilot phase that would impede NRC regulation of these facilities, the pilot sites selected were not representative of the entire DOE nuclear complex. In addition, the NRC raised concerns over the possible shared infrastructure, legacy materials disposition, site-specific regulatory aspects, and the necessary interfaces with OSHA and EPA. Although no decision has been reached at this date, all of these issues would impact the safety goal, and would likely require a phased and graded implementation schedule.

- In the materials arena, a total of 31 States have formal agreements with the NRC by which those States have assumed regulatory responsibility over byproduct, source, and small quantities of special nuclear material. There are over 15,000 specific radioactive materials licenses regulated by these States, as compared to 5,300 regulated by NRC. Several other States, including Oklahoma, Pennsylvania, and Wisconsin, continue to work toward becoming Agreement States in the next few years.

Although NRC has frequent contact with each of these States, and has developed budget estimates based on these contacts, there are a number of uncertainties that can lead to schedule slippages over time. If these slips occur, the budget forecasts of NRC licensing and inspection workloads could be perturbed. This could result in delays in licensing and inspection efforts, or tradeoffs in other areas that would compromise our effectiveness and efficiency.

- There will continue to be substantial public interest and involvement in the different elements of the nuclear materials safety arena. Opposition may require specific attention to program or licensee-specific factors.

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Public confidence in NRC and the regulated nuclear industry has varied over the years, and has varied across program arenas. This confidence is based on the public's perceptions regarding the regulator and the industry. Some of these perceptions are based on: 1) actual experience with NRC and its performance; 2) external factors (e.g., media reports, political commentaries, special interest group efforts, and industry group statements) that may or may not be closely linked to our actual performance, and 3), operational events such as accidents at Three Mile Island, and Chernobyl even though the impact on health and safety of the first accident was minimal and the facility involved in the second accident was outside NRC's regulatory control. To many, confidence (or lack of confidence) in the regulator and in the regulated industry cannot be clearly separated. Therefore, we recognize the potential that our activities and the licensees' activities jointly contribute to, or erode, the public's confidence and may cause us to take additional measures to assure the public.

- There are several major external factors impacting the effectiveness, efficiency, and realism performance goal. Congress, Agreement States, and licensees' actions, and technology advances may impact our ability to improve in effectiveness, efficiency, and realism.

If applicants submit significantly more requests for approvals than we forecast (new applications, amendments, or renewals) in the near term, this could cause backlogs that would impact the agency's ability to become more effective and efficient. Similarly, if new technologies arise that must be reviewed, approved, and inspected, it may be necessary for NRC to first become knowledgeable in the new areas before it can meet this goal.