



POLICY ISSUE

January 19, 1994

(NEGATIVE CONSENT)

ICY-94-011

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: MANAGEMENT DIRECTIVE ON USE OF COMMON PERFORMANCE INDICATORS
IN REVIEW OF THE AGREEMENT STATE AND REGIONAL MATERIALS
PROGRAMS

PURPOSE:

To provide the staff's proposed management directive on use of common performance indicators for Commission review and to inform the Commission of the staff's plan to implement the directive on a pilot basis in the regions and the Agreement States.

SUMMARY:

The staff has developed a management directive for the use of common performance indicators in review of the Agreement State and regional materials programs. A draft of the directive was provided to the Agreement States and the regions and their major comments have been reflected as appropriate. The directive uses five programmatic and five operational indicators, although the operational indicators do not figure directly in assessing the adequacy of State or regional programs. The staff is planning to implement the directive on a pilot basis, beginning in March, 1994, in two regions followed by two Agreement States. Implementation in the remaining Agreement State reviews will follow after the staff evaluates the initial regional and Agreement State reviews and makes any necessary changes to the process.

NOTE: TO BE MADE PUBLICLY AVAILABLE
WHEN THE FINAL SRM IS MADE
AVAILABLE

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BACKGROUND:

In SECY-93-300, the staff provided its plan and schedule for use of common performance indicators in review of the Agreement States and regional materials programs. The staff noted its intent to develop a management directive that would govern use of these indicators. A draft of that directive was provided to the Agreement States and the regions in October for review and comment. The directive was discussed at the All Agreement State meeting in Tempe, Arizona, on October 25 and 26, 1993. In addition, a few States have subsequently provided written comments on the directive, as have the regions and the Office for Analysis and Evaluation of Operational Data (AEOD).

DISCUSSION:

The staff has considered the written and oral comments it has received from the Agreement States, the NRC regions and AEOD and has made appropriate modifications to the directive. The proposed management directive, which is included as an enclosure, is now centered around five programmatic indicators and five operational, or output, indicators. The programmatic indicators include:

- o Status of Materials Inspection Program
- o Technical Staffing and Training
- o Technical Quality of Licensing Actions
- o Technical Quality of Inspections
- o Response to Incidents and Allegations

The operational indicators include:

- o Medical Misadministrations
- o Overexposures
- o Lost, Abandoned and Stolen Sources
- o Contamination Events
- o Contaminated Site Cleanup

The staff deleted the indicator "Status of Licensing" which was discussed in SECY-93-300. This decision was made primarily on comments received from the Agreement States as discussed below. In addition, for operational purposes, the staff combined two programmatic indicators ("Staffing and Staff Turnover" as well as "Training and Qualifications") into one indicator "Technical Staffing and Training." The staff also added a fifth operational or output indicator to address contamination events reported to the U.S. Nuclear

Regulatory Commission (NRC) or the Agreement States.

Comments Received from the Agreement States and Regions

The following paragraphs outline the major comments received on the proposed directive and the changes that were made to address those comments.

First, the Agreement States and, to a lesser degree, the regions thought that the indicator "Status of Licensing" should be deleted. This indicator addressed the overall performance of a State or region in terms of timeliness of completed licensing actions. A similar indicator is currently part of the Office of Nuclear Material Safety and Safeguards (NMSS) National Program Review (NPR) but is not part of the Office of State Programs' (OSP's) review of Agreement State radiation control programs. Many States believed that the indicator had only a tenuous link to public health and safety. The States also believed that inclusion of such an indicator could result in management pressure to meet timeliness goals with resulting dilution of attention to areas of greater health and safety significance. Accordingly, the staff proposes to delete this indicator from the set of common performance indicators. It will, however, continue to be addressed as part of NMSS' management review of the regions' implementation of the delegated materials program. It will also be partially addressed in Agreement State reviews by assessing the time required to process license renewals when evaluating technical quality of licensing actions.

The Agreement States also took issue with the concept described in SECY-93-300 of a graded approach to evaluation of their radiation control program performance. Under that approach, Agreement States and regions would have received an overall assessment of either Excellent, Satisfactory, Marginal or Unsatisfactory based on their aggregate performance relative to the performance indicators. Several thought that this approach was too much like NRC's Systematic Assessment of Licensee Performance (SALP) program for nuclear power plants and could be used in ways that are inappropriate for the Agreement States. For example, the results of the annual reviews could be used to develop a rank ordering of States in terms of their performance. The States noted that NRC's major concern should be adequacy to protect public health and safety and that value judgments beyond that are really not necessary or appropriate.

Instead, the Agreement States expressed a clear preference for an approach that would simply determine if a State were adequate or inadequate in terms of overall performance. The staff has considered this view and determined that an adequate/inadequate system has merit and is more consistent with the letter and spirit of the Agreement State program. Accordingly, the management directive has been revised to reflect this approach. Individual performance indicators will be rated in terms of three levels of performance: satisfactory, marginally satisfactory, and unsatisfactory. A Management Review Board (MRB) will consider the evaluations of all the performance indicators and make an overall determination of either adequate, marginally adequate, or inadequate, for each Agreement State or Regional program.

The Agreement States requested clarification of how the new approach embodied by the management directive would fit with past OSP review practices. More specifically, would OSP continue to conduct biennial reviews and annual review visits? Also, if problems with a program were identified early in the review cycle, the States were looking for assurance that they would be promptly communicated and not held as a surprise for the review. With respect to the first item, OSP does not envision continuation of the annual visits, unless specific conditions in a State warrant increased attention by NRC. On the latter item, it is not now OSP or NMSS practice to "hold" items until the time of review, and the staff envisions no change in this regard.

The issue of inclusion of sealed source and device (SS&D) reviews, also referred to as product evaluations, as part of the indicator on technical quality of licensing was also raised by the Agreement States. Several representatives offered the view that if the States were going to be evaluated in this regard, NRC should likewise look at its sealed source and device program, even though it is not a regional function but is reserved to Headquarters. The staff notes that the common performance indicators are intended to ensure a level of consistency between the reviews of the Regions' work and those of the Agreement States. Because SS&D reviews are a function reserved to Headquarters, they should not have been included in the draft management directive. Accordingly, the staff has removed them from the set of common performance indicators. This subject will continue to be reviewed by OSP for the Agreement States, but it will remain outside the common performance indicators. However, in recognition of the Agreement State comments, the staff will be examining various alternatives for evaluating the consistency and quality of Headquarters licensing actions such as SS&D reviews and low-level waste disposal facility licensing.

The use of operational, or output, indicators was perhaps the most sensitive area in the view of the Agreement States. The States continue to have serious concerns about the utility and use of the output indicators, in spite of the staff's clarification that the information will initially be used only for trending purposes. Region I echoed the views of many of the Agreement States when it said:

" (the operational indicators) are not appropriate indicators for assessing the performance of a regulatory program or for comparing one program to another. No regulatory program can entirely preclude these events from occurring. We believe that the regulatory programs of the NRC and the States have been successful in reducing the number of these events to the point where most of these events are essentially random in nature and have little to do with the quality of the regulatory program as implemented by the Regions or the States."

The staff noted many of the problems and concerns associated with the operational indicators in SECY-93-300 and intends to continue with its plan to collect output information during the first year with a primary objective of establishing a baseline for future years.

The Agreement States also felt that an Agreement State representative should be a member of the Management Review Board (MRB). Because the MRB would be making statutorily-required decisions on adequacy and compatibility, which are NRC's responsibility under Section 274j of the Atomic Energy Act, as amended, the staff believes that membership on the MRB should be limited to NRC employees. However, in the interest of providing visibility of MRB proceedings the staff recommends that the MRB meetings: 1) be open public meetings that would allow Agreement State representatives and others to be present; and 2) afford the opportunity for presentation of oral comments.

A number of other Agreement State comments were considered by the staff. The States were concerned about the staff's proposed requirement under the indicator, Technical Quality of Inspections, to have States submit inspection reports to the NRC on a routine basis. Upon reflection, the staff agrees that this would be an unnecessary paperwork burden on the States and essentially the same result could be obtained by examining inspection reports during the onsite review. The Agreement States also requested clarification of timeliness in issuing inspection findings under the indicator, Status of Materials Inspection Program. Accordingly, the staff clarified this area, using the requirements contained in Inspection Manual Chapter 0610-10. Finally, the States had a more general concern that the use of performance indicators could deteriorate into a "bean-counting" exercise. The staff believes that deletion of the indicator on "Status of Licensing" from the management directive, as discussed above, will largely address this concern.

Review of Non-Common Performance Indicators

Both NMSS and OSP have programmatic responsibilities that extend beyond the common performance indicators. Accordingly, the staff plans to use the common performance indicators, supplemented appropriately, to evaluate both Agreement State and regional programs. For example, NMSS will evaluate the regions on operating plan commitments relative to nuclear materials, fuel cycle and safeguards, and low-level waste and decommissioning issues. Similarly, OSP will look at the States with respect to adequacy issues that are broader than those addressed by the common performance indicators, such as regulations and laboratory support. If concerns arise, additional detailed reviews may be performed in other areas such as budget or administrative procedures. In addition, OSP will be examining the compatibility of the Agreement State program which is also outside the common indicators. The results of these non-common evaluations will be provided to the MRB for its consideration.

The criteria and procedures to be used by the respective offices in executing their responsibilities, however, are not within the purview of the management directive. SECY-93-349 identifies the areas that will be addressed in reviews of Agreement States for adequacy and compatibility. Non-common areas to be addressed in the regional reviews will include the subjects mentioned above as well as others being developed.

Role of the Management Review Board

The MRB will play a central role in the process of Agreement State and Regional reviews. Membership of the MRB will consist of a group of senior NRC managers, or their designees, to include:

- o Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support;
- o Director, NMSS;
- o Director, OSP;
- o Director, AEOD; and
- o The General Counsel

The MRB will consider the review team's findings for each of the programmatic indicators as well as supplemental indicators as mentioned above. Based on that consideration, the MRB will make determinations of: 1) adequacy, with respect to the regions; and 2) adequacy and compatibility with respect to the Agreement States. The broad views and interests afforded by the membership of the MRB would help ensure independence and consistency in reviews, especially during the first year of the program.

The staff has considered various options in terms of the MRB's consideration of the review team's findings. The first would be to issue the draft report to the region or State under signature of the NMSS or OSP Director, without a conclusion on overall adequacy, for factual review including addition of mitigating factors. After evaluation of the regional or State comments, the revised report would be sent to the MRB for its consideration. The second option would be to send the draft report directly to the MRB for an initial finding of adequacy and then provide it to the region or State for comment. The MRB would make its final determination after consideration of any regional or State comments. The staff prefers the first option in that it provides the MRB with the maximum information in making its determination and allows quicker issuance of draft reports.

Implementation

The management directive provides overall guidance for implementation of the program. However, specific procedures, review checklists and guidance, and questionnaires need to be developed. The staff is proceeding to develop these program documents.

The first reviews using the approach described in the directive will take place on a pilot basis beginning in March, 1994 in the regions and the Agreement States. Following this pilot use of the directive, the staff will evaluate the process, make any necessary revisions to procedures, questionnaires, and checklists, and will then proceed to use the performance indicators in review of the Agreement States. Modifications of the

performance indicators may also be necessary when the new Agreement State adequacy/compatibility policy is finalized. Until March, 1994, already-scheduled Agreement State reviews will proceed under the current approach.

With respect to organization, the staff continues to believe that a high degree of inter-office (NMSS and OSP) participation in the reviews is essential. For purposes of the pilot program, the staff plans to use the same group of four individuals to evaluate common performance indicators. The staff ultimately envisions using two teams of four individuals from a pool of 12 qualified persons to be selected from OSP, the regions and NMSS. The staff also believes that such an approach will lead to valuable cross-fertilization between OSP, NMSS and the regions. The staff had considered involvement of Agreement State personnel as part of the review teams, but that option was not considered feasible in the near term. In the longer term, the staff will work with the Office of General Counsel in exploring the potential of Agreement State involvement on the review teams.

RESOURCES:

For reviews conducted on a biennial basis, the staff estimates that approximately 10 full time equivalents (FTE) would be required to conduct reviews of the common performance indicators. Preparation of an annual report, coordination with the Organization of Agreement States (OAS) and briefings of senior management and the Commission could require an additional 1 FTE. In addition, because the common performance indicators would represent an expansion of the current NPR, an additional 1 FTE may be required for the regions. NMSS has budgeted approximately 4 FTE in FY94 for conduct of the NPR. OSP has budgeted approximately 8 FTE in FY94 for review of the Agreement State programs. Accordingly, the staff believes this new approach can be implemented on a biennial frequency with existing resources.

COORDINATION:

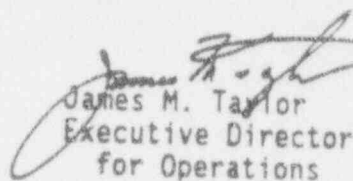
This paper has been coordinated with the Office of the General Counsel, which has no legal objection. Resource considerations have been coordinated with the Office of the Controller.

RECOMMENDATION:

That the Commission:

1. Note that unless directed otherwise, within 10 business days, the staff intends to:
 - Publish the enclosure in Management Directive format as part of the NRC Management Directives system; and

- Implement the directive beginning in March 1994 on a pilot basis in Regions I and II, and then in two Agreement States (to be determined).
- Issue a press release announcing the use of common performance indicators in review of the Agreement State and NRC Region materials programs, and highlighting the plan for implementation.


James M. Taylor
Executive Director
for Operations

Enclosure:
Management Directive

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Friday, February 4, 1994, that the Commission, by negative consent, assents to the action proposed in this paper.

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(NMSS/OSP)

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP)

DIRECTIVE 5.6

Policy.
(5.6-01)

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to evaluate the Regional materials programs and Agreement State Radiation Control Programs in an integrated manner using common performance indicators. The integrated materials performance evaluation program (IMPEP) described in this directive will help assure that the public health and safety is being adequately protected throughout the United States. This directive and its associated handbook define the objectives, responsibilities, terms, and procedures for conduct of this program.

Objectives.
(5.6-02)

To establish the process by which the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs (OSP) conduct their biennial assessments of the NRC regions and Agreement States, in order to determine the adequacy of their programs. (021)

To provide NRC and Agreement State management with a more systematic and integrated approach to evaluate the strengths and weaknesses of their nuclear material licensing and inspection programs, as conducted by the NRC regional offices and the Radiation Control Programs in each of the Agreement States. (022)

To provide significant input in the regulatory decision-making process, and indicate areas in which the NRC and States should dedicate more resources or management attention. In this way, the assessments should be instrumental in improving State or regional performance, thus ultimately leading to improved licensee performance. (023)

Organizational Responsibilities and Delegations of Authority
(5.6-03)

The Executive Director for Operations (or designee) (EDO)
(031)

- o Provides oversight for the activities described herein. (a)
- o Chairs Management Review Boards. (b)
- o Signs final reports issued to each region and State. (c)

Enclosure

The Director, Office of Nuclear Material Safety and Safeguards (NMSS) and the Director, Office of State Programs (OSP)
(032)

- o Implement the requirements of this directive within NMSS and OSP. Provide staffing support and training for review teams, as needed. (a)
- o Establish a schedule and develop a detailed review regimen for conducting the reviews in each region and State. (b)
- o Monitor the IMPEP process; evaluate and develop IMPEP policy, criteria, and methodology, and assess the uniformity and adequacy of the implementation of the program. (c)
- o Issue draft reports and prepare final reports for each region and State for consideration by Management Review Board and signature by the EDO. (d)
- o Participate as needed on Management Review Boards. (e)
- o Prepare an annual report on the status of the national materials program. The report is to be coordinated with the Organization of Agreement States, discussed at the NRC Senior Management Meeting, and presented to the Commission in an annual public meeting. (f)

The General Counsel
(033)

- o Participates as needed on Management Review Boards (a)

The Director, Office for Analysis and Evaluation of Operational Data (AEOD)
(034)

- o Provides the operational performance data for each State and region (e.g. misadministrations, overexposures, number of lost or abandoned devices, or contamination events) in a format suitable for analysis by the review teams. (a)
- o Participates as needed on Management Review Boards. (b)

Regional Administrators
(035)

- o Implement the requirements of this directive and handbook within their respective regions. (a)
- o Provide staffing support for review teams, as needed. (b)

Applicability.
(5.6-04)

This directive and handbook apply to and must be followed by all NRC headquarters and regional employees who are responsible for and participate in the IMPEP. (a)

This directive and handbook apply to regulation of byproduct, source, and special nuclear materials safety activities within a set of common performance indicators. Certain non-reactor functions that continue to be conducted from NRC Headquarters, such as fuel cycle licensing, uranium and thorium milling, sealed source and device reviews, and safeguards activities are excluded from this set of indicators since they are not common to regional and State activities. This exclusion does not prohibit NMSS and OSP from using other indicators and/or performance standards to supplement those described in this directive. (b)

Handbook.
(5.6-05)

Handbook 5.6 presents the performance indicators that will be used, the performance standards against which these indicators will be evaluated, and the frequency and process sequence to be employed. The Glossary in the handbook also defines some of the key terminology.

References.
(5.6-06)

1. "Inspector Qualifications". NRC Inspection Manual Chapter 1245.
2. Office of Nuclear Material Safety and Safeguards (NMSS) Policy and Guidance Directive 91-4, "Materials Licensing Reviewer Training and Qualification Requirements," dated September 13, 1991.
3. "Materials Inspection Program". NRC Inspection Manual Chapter 2800.
4. "Purpose and Scope," 10 CFR 35.2.
5. Office of State Programs (OSP) Policy Statement on Reviewing State Radiation Control Programs, April 30, 1992.
6. "Definitions," 10 CFR 20.1103.
7. "Definitions," 10 CFR 170.3.

8. "Reports of Theft or Loss of Licensed Material," 10 CFR 20.2201.
9. "Notification of Incidents," 10 CFR 20.2202.
10. "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits," 10 CFR 20.2203.

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP)

HANDBOOK 5.6

Introduction.

In February 1993, the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support (DEDS) established a task force to conduct a comprehensive evaluation of the difference in the approach used to examine the materials programs conducted by NRC and the Agreement States. As part of its effort, the task force identified a set of seven common programmatic performance indicators that could serve as the elements of a more integrated performance assessment process.

A short time later, after comments were received from the DEDS, the regions and other offices, including the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs (OSP), four operational indicators were added to the original seven.

In October 1993, a first draft of this directive and handbook was circulated for comment to other offices, the regions, and to all Agreement States. A number of comments were received, which resulted in some modifications to the original list of indicators. As a result of those modifications, the directive now employs five programmatic and five operational, or output, indicators. The programmatic indicators are as follows:

- Status of Materials Inspection Program
- Technical Staffing and Training
- Technical Quality of Licensing Actions
- Technical Quality of Inspections
- Response to Incidents and Allegations

The operational indicators, however, will not be used directly in evaluating programmatic adequacy. Rather, they will be used in the short term to establish a performance baseline and in the longer term for trending analysis that may be of value in assessing performance. The operational indicators are as follows:

- Medical Misadministrations
- Overexposures
- Lost, Abandoned or Stolen Sources
- Contamination Events
- Contaminated Sites

PART I

Evaluation

Evaluation Frequency (A)

NRC will review the performance of each region and each Agreement State on a biennial basis. The schedule for conducting each regional or Agreement State visit will be developed by the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs (OSP) in coordination with the regions and States.

Evaluation Process Sequence (B)

The typical evaluation process is summarized below:

- o Develop review schedule for the year. (1)
- o Assemble and train team members. (2)
- o Designate team leader and members for each scheduled review. (3)
- o Review completed licensing actions on ongoing basis to help focus reviews. (4)
- o Transmit questionnaires to affected regions and States. (5)
- o Provide copy of questionnaire responses and most current performance data summary to team members. (6)
- o Conduct inspection accompaniments. (7)
- o Conduct on-site portion of IMPEP, using the criteria specified in this handbook, and any performance review procedures, in conjunction with any customized review elements. (8)
- o Prepare draft IMPEP reports, with recommendation for overall performance evaluation, for Office Director signature. (9)
- o Issue the draft reports. (10)
- o Review and consider written comments received from the regions or Agreement States. (11)
- o Conduct Management Review Board meetings. (12)
- o Issue final reports, include the written responses received and any changes to the report based on consideration of the written responses, and a summary of Management Review Board findings. (13)

PART II

Performance Indicators

General (A)

The following paragraphs provide a description of the performance indicators to be evaluated on a biennial basis for each region and each Agreement State. The evaluation criteria (i.e. performance standards) against which these indicators are to be assessed are described in Part III of this handbook. Reviews of regional inspection program status performance and each of the operational performance indicators will also be evaluated on a state-by-state basis, to the extent possible, to allow comparison with Agreement State data. (1)

The performance indicators should be used as a starting point of inquiry. This, in turn, should lead program evaluators to a more careful examination of the underlying conditions, or "root causes" of potential problem areas. Evaluators may find correlations exist between two or more performance indicators. In this situation, the impact of individual performance symptoms could be compounded when combined with others. Conversely, a regulatory program measured as potentially weak against one particular indicator could, nonetheless, be rated as strong overall, if there are sufficient mitigating factors with respect to other indicators. (2)

Programmatic Indicators (B)

Performance Indicator 1- Status of Materials Inspection Program (1)

Periodic inspections of licensed operations are essential to assure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections depends on the amount and kind of material, the type of operation licensed, and the results of previous inspections. The capability of maintaining and retrieving statistical data on the status of the compliance program is necessary. Information showing the percentage of overdue inspections is, perhaps, the most meaningful measure of the status of a State or region's materials inspection program although reviews should also examine specific cases where the inspection frequency has been significantly exceeded (i.e., by more than 100%). The terms "materials inspection" and "overdue inspection" are defined in the Glossary.

Performance Indicator 2- Technical Staffing and Training (2)

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and thus could affect public health and safety. (a)

For this performance indicator, qualitative as well as quantitative

measures must be considered. In particular, the reason for apparent trends in staffing must be explored. Is the rate of turnover and the degree of under-staffing symptomatic of a chronic problem or is it merely a short-term phenomenon? Why is turnover high? What steps are being taken to address this? What impact is it having on other performance indicators? (b)

Review of staffing also requires a consideration and evaluation of the levels of training and qualification of the technical staff. New hires need to be technically qualified. Professional staff should normally have bachelor's degrees or equivalent training in the physical and/or life sciences. Training requirements for NRC inspectors are specified in Inspection Manual Chapter (IMC) 1245, and for NRC materials licensing reviewers in NMSS Policy and Guidance Directive 91-4. The requirements include a combination of classroom requirements and practical on-the-job training. Some regions impose additional requirements on certain license reviewers or inspectors depending upon their individual responsibilities, based on the types of licenses they review and/or inspect. (c)

In addition, the qualification process for NRC materials program inspectors includes demonstration of knowledge on relevant sections of the Code of Federal Regulations, completion of a Qualifications Journal, and appearance before a Qualifications Board. The equivalent of these requirements should be present in Agreement State programs. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel. (d)

The findings from these reviews will contribute to establishing an integrated training approach between the license reviewers and inspectors in the NRC and the Agreement States, based on the core courses used for State personnel, the requirements listed in IMC 1245, or some combination of the two. (e)

Performance Indicator 3- Technical Quality of Licensing Actions (3)

It is necessary in licensing byproduct, source, and special nuclear materials that the regulatory agency obtain information about the proposed use of the nuclear materials, facilities and equipment, training and experience of personnel, and operating procedures appropriate for determining that the applicant can operate safely and in compliance with the regulations and license conditions. An acceptable licensing program includes: preparation and use of internal licensing guides and policy memoranda to assure technical quality in the licensing program (when appropriate, NRC Guides may be used); prelicensing inspection of complex facilities; and the implementation of administrative procedures to assure documentation and maintenance of adequate files and records. (a)

Performance Indicator 3 evaluates the technical quality of the licensing program, based on a year-round audit of completed actions, as well as an indepth onsite review of a representative cross-section of each type of action, and various types of licenses. Technical quality includes not only the review of completed actions, but also an examination of any

renewals which have been pending for more than a year since failure to act on such requests may have health and safety implications. To the extent possible, the onsite review should also capture a representative cross-section as completed by each of the reviewers in the region or State. (b)

Performance Indicator 4- Technical Quality of Inspections (4)

This performance indicator provides the qualitative balance to Performance Indicator 1 above, which looks at the status of the inspection program on a quantitative basis. Reviews of programs under this indicator focus on the scope, completeness, and technical accuracy of completed inspections, appropriate disposition of inspection findings, and related documentation. Review teams will conduct indepth, onsite reviews of a cross-section of completed inspection reports performed by different inspectors. Inspector accompaniments by review teams will be used to evaluate the knowledge and capabilities of regional and Agreement State inspectors. In addition, review teams will verify that supervisors conduct accompaniments of inspectors on at least an annual basis to provide management quality assurance.

Performance Indicator 5- Response to Incidents and Allegations (5)

The quality, thoroughness, and timeliness of a regulator's response to incidents and alleged incidents can have a direct bearing on public health and safety. A careful assessment of incident response procedures, actual implementation of these procedures, internal and external coordination, and followup procedures will be a significant indicator of the overall quality of the program.

Operational Performance Indicators (C)

Operational performance data will be collected during the first review cycle on misadministrations, overexposures, lost and abandoned sources, and contamination events only in order to establish a baseline. For contaminated sites, the review should be limited in the first assessment cycle to whether or not a State has in place a program, and is making progress in the identification and cleanup of contaminated sites. The first cycle of reviews will provide a benchmark for comparison purposes in the second cycle and over the long term for trending. In the first cycle of the program, Regional and Agreement State evaluations will be based on the five programmatic indicators previously discussed.

Performance Indicator 6- Medical Misadministrations (1)

This performance indicator documents the rate of misadministrations, as defined in 10 CFR Part 35.2, or equivalent State regulation based on the number of specific medical use licenses.

Performance Indicator 7- Overexposures (2)

This indicator documents the rate of overexposures, as defined in the Glossary, based on the number of specific licenses.

Performance Indicator 8- Lost, Abandoned, or Stolen Sources (3)

This indicator documents the rate at which specific licensees or classes of licensees lose or abandon sources, as these terms are defined in the Glossary.

Performance Indicator 9- Contamination Events (4)

This indicator documents the number of contamination events, as this term is defined in the Glossary.

Performance Indicator 10- Contaminated Sites (5)

This indicator documents the progress made by a Region or State in identifying and taking appropriate action to decontaminate sites believed or known to be contaminated, as the term is defined in the Glossary.

PART III

Evaluation Criteria

Regions and States will be evaluated using the performance indicators described in Part II of this handbook. The following is a discussion of the evaluation criteria.

Indicator 1- Status of Materials Inspection Program * (A)

Satisfactory. Core licensees (those with inspection frequencies of three years or less) and non-core licensees (the rest) are inspected at regular intervals in accordance with frequencies prescribed in NRC Inspection Manual Chapter (IMC) 2800. No more than 10% of licensees are inspected at intervals which exceed the prescribed intervals by more than 25%. Inspections of new licensees are generally conducted within 6 months of license approval, or in accordance with Schedule A of IMC 2800-04-03 for those new licensees not possessing licensed material. A large majority of the inspection findings are communicated to licensees in a timely manner (30 calendar days as specified in IMC 0610-10). (1)

Marginally Satisfactory. More than 10% of the core licensees are inspected at intervals which exceed the prescribed intervals by more than 25%. Inspections of new licensees are frequently not conducted within 6 months of license approval. Some of the inspection findings are delayed, or not communicated to licensees within 30 days. (2)

Unsatisfactory. More than 25% of the core licensees are inspected at intervals which exceed the prescribed intervals by more than 25%. Inspections of new licensees are frequently delayed, as are the inspection findings. (3)

Category N. Special conditions exist which provide adequate justification for withholding a rating. For example, an unforeseen event or emergency with significant health and safety consequences may have required a temporary diversion of resources from the core inspection program. However, these programmatic adjustments are well-thought out, and properly coordinated with NMSS or Agreement State management. (4)

* Note: For the regions, this will be evaluated on a state-by-state basis, but the assessment will be based on cumulative performance.

Indicator 2- Technical Staffing and Training (B)

Satisfactory. Review indicates implementation of a well-conceived and balanced staffing strategy throughout the assessment period, and demonstrates the qualifications of the technical staff. This is indicated by the presence of most of the following features: (1)

o balance in staffing the licensing and inspection programs (a)

- o few, if any, vacancies, especially at the senior-level positions (b)
- o prompt management attention and review, such as development of a corrective action plan to address problems in high rates of attrition or positions being vacant for extended periods (c)
- o qualification criteria for hiring new technical staff have been established and are being followed. Staff would normally be expected to have bachelor's degrees or equivalent training in the physical and/or life sciences. Senior personnel should have additional training and experience in radiation protection commensurate with the types of licenses they issue or inspect. (d)
- o license reviewers and inspectors are trained and qualified in a reasonable time period (e) *
- o management commitment to training is clearly evident (f)

Marginally Satisfactory. Review determines the presence of some of the following conditions: (2)

- o significant staff turnover relative to the size of the program (a)
- o vacant positions not readily filled (b)
- o little evidence of management attention or actions to deal with staffing problems (c)
- o some of the licensing and inspection personnel not making prompt progress in completing all of the training and qualification requirements (d)
- o the lack of well-defined training and qualification standards (e)
- o new staff is hired with little education or experience in physical and/or life sciences, or materials licensing and inspection (f)

Unsatisfactory. Review determines the presence of chronic or acute problems related to some of the following conditions, which cause concerns about their likely impacts on other performance indicators (3)

- o significant staff turnover relative to the size of the program (a)
- o vacant positions not filled for extended periods (b)

* For the Regions, this means there has been, and continues to be, a clear effort to adhere to the requirements and conditions specified in NMSS Policy and Guidance Directive 91-4, NRC Inspection Manual Chapter 1245, and applicable Qualifications Journals or to receive equivalent training elsewhere. For the Agreement States, equivalent requirements should be in place and followed.

o little evidence of management attention or actions to deal with staffing problems (c)

o most of the licensing and inspection personnel not making prompt progress in completing all of the training and qualification requirements (d)

o new staff members are hired without having scientific or technical backgrounds that would equip them to receive health physics training (e)

Category N. Special conditions exist which provide justification for withholding a rating. For example, there has been a substantial management effort to deal with staffing problems. NMSS or OSP has been kept informed of the situation, and discernable recent progress is evident. (4)

Indicator 3- Technical Quality of Licensing Actions (C)

Satisfactory. Review of completed licenses and a representative sample of licensing files indicates that license reviews are generally thorough, complete, consistent, and of acceptable technical quality. Health and safety issues are properly addressed. License reviewers almost always have the proper signature authority for the cases they review. Special license tie-down conditions are usually stated clearly and are inspectable. Deficiency letters are well-written and used at the proper time. Reviews of renewal applications demonstrate thorough analysis of a licensee's inspection and enforcement history. Applicable guidance documents are available to reviewers in most cases, but improper or inconsistent adherence to published guidance may be evident occasionally with some of the reviewers. Nonetheless, no potentially-significant health and safety issues can be linked to licensing practices. (1)

Marginally Satisfactory. Review indicates that licensing actions occasionally fail to fully address important health and safety concerns or indicates repeated examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality and adherence to existing guidance in licensing actions. (2)

Unsatisfactory. Review indicates that licensing actions frequently fail to address important health and safety concerns or indicates chronic problems with respect to thoroughness, completeness, consistency, clarity, technical quality and adherence to existing guidance in licensing actions. (3)

Category N. Not applicable. (4)

Indicator 4- Technical Quality of Inspections (D)

Satisfactory. Accompaniments of inspectors combined with an onsite review of a representative cross-section of completed inspection files indicates inspection findings are usually well-founded and well-documented throughout the assessment period. A review of inspector field notes or completed reports indicates that most inspections are complete and reviewed promptly by supervisors or management. Procedures are in place and normally used to help identify root causes and poor licensee performance. In most instances, followup inspections address previously identified open items and/or past violations. Inspection findings generally lead to appropriate and prompt regulatory action. Supervisors accompany nearly all inspectors on an annual basis. (1)

Marginally Satisfactory. Review indicates that some inspections do not address potentially important health and safety concerns or it indicates periodic problems with respect to completeness, adherence to procedures, management review, thoroughness, technical quality and consistency. Review indicates that findings in inspection reports and inspection files are, on occasion, not well-founded or well-documented, and the review does not demonstrate an appropriate level of management review. Accompaniment of inspectors by supervisors are performed non-systematically. Follow-up actions to inspection findings are often not timely. (2)

Unsatisfactory. Review indicates that inspections frequently fail to address potentially important health and safety concerns or it indicates chronic problems exist with respect to completeness, adherence to procedures, management review, thoroughness, technical quality and consistency. Accompaniments of inspectors are infrequently performed. Follow-up actions to inspection findings are often not timely and appropriate. (3)

Category N. Not applicable. (4)

Indicator 5- Response to Incidents and Allegations (E)

Satisfactory. Incident response and allegation procedures are in place and followed in nearly all cases. Actions taken are appropriate, well-coordinated, and timely in most instances. Level of effort is usually commensurate with potential health and safety significance of incident. Investigative procedures are appropriate for incident. Corrective (enforcement or other) actions are adequately identified to licensees promptly and appropriate followup measures are taken to assure prompt compliance. Followup inspections are scheduled and completed, if necessary. Notification to NMSS, AEOD, or OSP, and others as may be appropriate, is usually performed in a timely fashion. (1)

Marginally Satisfactory. Incident response and allegation procedures are in place but occasionally not practiced in a detailed fashion. Performance is marginal in terms of resolving potential public health and safety issues, but not as well-coordinated, complete or timely as

would be required under the "Adequate" performance standard. (2)

Unsatisfactory. Review indicates frequent examples of response to incidents to be incomplete, inappropriate, poorly-coordinated, or not timely. As a result, potential health and safety problems persist. (3)

Category N. Not applicable. (4)

PART IV

Programmatic Assessment

A Management Review Board (MRB), will make the overall assessment of each Region's or State's program based on the draft report and recommendations prepared by the team that conducted the review of that Region or State. The MRB will find a program to be adequate, marginally adequate or inadequate. The MRB will consider all the information gathered by the review team, including any unique circumstances as well as non-common indicators. (For Agreement States, a compatibility determination may also be included in this report, but the criteria for making this determination will be included in a policy statement being developed separately by the Office of State Programs).

(1)

The MRB will consist of a group of senior NRC managers, or their designees, to include:

- o the Executive Director for Operations
- o the Director of the Office of Nuclear Material Safety and Safeguards
- o the Director of the Office of State Programs
- o the Director of the Office of Analysis and Evaluation of Operational Data
- o the General Counsel

Glossary

A number of terms used throughout this handbook require standard definitions. For other terms not listed below, the definitions shown in Chapter 10 of the Code of Federal Regulations, the NRC Inspection Manual, or NRC's Management Directives Systems should be used. It is necessary to note that some Agreement States or regions may not define these terms identically. In such cases, the review team will highlight any differences in its review but draw its conclusions and make its assessments based on the definitions used by that State or Region at the time of the review.

Allegation. As used in this handbook, the term means a declaration, statement, or assertion of impropriety or inadequacy associated with regulated activities, the validity of which has not been established. This term includes all concerns identified by sources such as the media, individuals or organizations, and technical audit efforts from Federal, State or local government offices regarding activities at a licensee's site. Excluded from this definition are matters being handled by more formal processes such as 10 CFR 2.206 petitions, hearing boards, appeal boards, and so forth.

Contaminated Site. Any inactive site, or inactive portion of a site with other active uses of licensed material contaminated with radioactive material in excess of the appropriate release criteria for unrestricted use.

Contamination Event. As used in this handbook, this term applies to events in which releases of radioactive material occur that require reporting in accordance with 10 CFR 20.2202 (a)(2) and (b)(2).

Incident. As used in this handbook, this term applies to an event that may have caused or threatens to cause conditions described in 10 CFR 20.2202 (old 20.403), 10 CFR 30.50, 10 CFR 40.60, 10 CFR 70.50 or the equivalent State regulations.

Lost, Abandoned, or Stolen Sources. As used in this handbook, this term applies to any occurrences which must be reported as specified in 10 CFR 20.2201 (old 20.402) or the equivalent State regulation.

Materials Inspection. NMSS and OSP are working on additional clarification on what does and does not constitute a materials program inspection. Until that clarification is issued, the definitions in 10 CFR 170.3 (1) and (2), and in NRC Inspection Manual Chapter 2800, Paragraph 04.06, should be used to determine what constitutes an inspection. In addition, Agreement State hand-delivery of new licenses may constitute initial inspections. The term includes both routinely-scheduled and reactive inspections.

Materials Licensing Action. This term includes reviews of applications for new byproduct materials licenses, license amendments, renewals, and license terminations.

Overdue Inspections. Currently, NRC defines this term based on guidance in Inspection Manual Chapter 2800, Paragraph 09.05. Many States use different definitions. For purposes of this Directive, a materials license will be considered overdue for inspection in the following cases:

- A new licensee that possesses licensed material has not been inspected within 6 full months of license issuance. Licensees not possessing such material have not been inspected in accordance with Schedule A of Inspection Manual Chapter (IMC) 2800-04-03.

- An existing license is more than 25% beyond the interval defined in Inspection Manual Chapter 2800, Table 1.

Determinations of overdue inspections will not be based on any inspection frequencies established by States or regions that are more stringent than those contained in IMC 2800. The IMC 2800 frequencies will generally be used as the yardstick for determining if an inspection is overdue.

Overexposure. This term is referred to in 10 CFR 20.2203 (old 20.405) or the equivalent State regulation. In this handbook, the term excludes certain non-reactor categories of licensees such as independent spent fuel storage licensees and fuel fabricators and processors who may also be required to report overexposures.