

DRAFT OMB SUPPORTING STATEMENT FOR NRC POLICY STATEMENT,
“CRITERIA FOR GUIDANCE OF STATES AND NRC IN
DISCONTINUANCE OF NRC REGULATORY AUTHORITY
AND
ASSUMPTION THEREOF BY STATES THROUGH AGREEMENT,”
MAINTENANCE OF EXISTING AGREEMENT STATE PROGRAMS,
REQUESTS FOR INFORMATION THROUGH THE INTEGRATED MATERIALS
PERFORMANCE EVALUATION PROGRAM (IMPEP) QUESTIONNAIRE,
AND
AGREEMENT STATE PARTICIPATION IN IMPEP
(3150-0183)

EXTENSION

Description of the Information Collection

States seeking to regulate certain Atomic Energy Act (Act) radioactive materials are requested to submit information directly to the Nuclear Regulatory Commission’s (NRC), Office of Nuclear Material Safety and Safeguards (NMSS) related to the management, structure, and performance of their radiation control programs (RCPs) in accordance with the terms and conditions of Section 274 of the Act and the criteria identified in the NRC Policy Statement, “Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof By States Through Agreement” (noticed in the *Federal Register* 46 FR 7540, January 23, 1981; as amended by policy statements published at 46 FR 36969, July 16, 1981; 48 FR 33376, July 21, 1983; and 82 FR 48535, October 18, 2017). This policy statement identifies the factors considered by NRC prior to approving new or amended Agreements. A State that has entered into such an Agreement is referred to as an Agreement State (AS). Presently, there are 39 AS, which regulate approximately 88 percent of the byproduct, source, and certain special nuclear material licensees in the United States.

The NRC is required to evaluate AS programs to ensure that its RCP remains adequate and compatible with the requirements of Section 274 of the Act. The NRC implemented a process, noticed in the *Federal Register*, known as the Integrated Materials Performance Evaluation Program (IMPEP) to evaluate NRC Regional licensing and inspection programs and AS RCPs for adequacy and compatibility. These performance-based reviews are conducted in accordance with Management Directive 5.6, “Integrated Materials Performance Evaluation Program (IMPEP)” and are routinely conducted approximately every 4 years. A questionnaire (Attachment 1) is used by IMPEP review teams to gather information about the RCP to assist the IMPEP team in conducting the evaluation of the adequacy of the State’s program to protect public health and safety and determining the compatibility of the program with the NRC’s regulatory program. The IMPEP questionnaire also includes a request for material to be available for the on-site portion of the IMPEP review. The ASs requested that such a questionnaire be developed to facilitate the IMPEP review.

The questionnaire requests information about the following RCP performance indicators:

- a. Technical Staffing and Training
- b. Status of Materials Inspection Program
- c. Technical Quality of Inspections
- d. Technical Quality of Licensing Actions
- e. Technical Quality of Incident and Allegation Activities
- f. Legislation, Regulations, and Other Program Elements
- g. Sealed Source and Device Evaluation Program
- h. Low-level Radioactive Waste Disposal Program
- i. Uranium Recovery Program

A. JUSTIFICATION

1. Need For and Practical Utility of the Collection of Information

Section 274 of the Act permits the NRC to relinquish portions of its regulatory authority to States. The mechanism for this transfer of authority is a formal Agreement between the NRC and the Governor of the State and issuance of an exemption to licensed persons in accordance with 10 CFR 150.10. The Act requires the NRC to perform periodic reviews of each AS to ensure that its RCP remains adequate and compatible with the requirements of the Act.

The information covered by this request is required by NRC in order to evaluate: (1) the adequacy of a State's RCP to protect public health and safety, and (2) the compatibility of a State's RCP with NRC's program.

2. Agency Use of Information

As required by the Act, information received from the States under this program assists the NRC in determining: (1) the adequacy of a State's RCP to protect public health and safety, and (2) the compatibility of a State's RCP with NRC's program.

3. Reduction of Burden Through Information Technology

The NRC has issued [Guidance for Electronic Submissions to the NRC](#) which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. All responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

These information collections do not affect small businesses.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

The collection of information less frequently than the periodic IMPEP reviews of ASs, which are currently conducted approximately every 4 years, would significantly reduce the efficiency and effectiveness of those reviews. The NRC believes that gathering information at the time of the review assures that the determination of the adequacy to protect public health and safety and the compatibility of an AS program with NRC's program is based on current information. Collecting this information less frequently, or not at all, would significantly decrease the NRC's ability to determine AS adequacy to protect public health and safety and compatibility with NRC's regulatory program.

7. Circumstances Which Justify Variation from OMB Guidelines

There is no variation from OMB guidelines.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register*.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential or proprietary is requested.

11. Justification for Sensitive Questions

The NRC does not require the State to submit any sensitive information.

12. Estimated Burden and Burden Hour Cost

This information collection affects 41 respondents during the 3-year clearance period: 39 existing ASs, 1 AS applicant under review, and 1 anticipated new application.

Questionnaire

The NRC has requested approximately 12 of the existing 39 ASs to respond to an IMPEP questionnaire annually. They expend an average of 53 hours per AS program, or a total of 636 hours annually, for a cost of \$184,440 (636 hours x \$290/hour). This estimate includes the recordkeeping burden for the IMPEP questionnaire. This burden does not include the burdens to AS licensees, which are included in OMB clearances for each 10 CFR Part.

Policy Statement and Maintenance of Program

New AS Applications. The NRC estimated that a State seeking an Agreement expends approximately 6,750 hours over a 3-year period or 2,250 hours annually (6,750 hours divided by 3 years) preparing a proposal for a new Agreement. As a planning assumption the NRC staff anticipates receiving one new AS application over the next three years at an annual cost of \$652,500 (2,250 hours x \$290/hour). There is no additional recordkeeping burden associated with new AS applications.

Participation in IMPEP Reviews. IMPEP review teams are composed of NRC and AS staff. The AS team members participate annually in 10 materials program IMPEP reviews and 2 AS follow-up IMPEP reviews. Each review is estimated to take 180 hours for a total of 2,160 staff hours per year (180 hours x 12 reviews). This estimate is based on the length of time for States to conduct the entire review (prepare, conduct, and document the review). The NRC estimated that 20 percent or a total of 432 hours annually (0.2 x 2,160 hours) of this burden is spent on the information collection activities. Thus, the average burden per review is 36 hours (432 hours per year divided by 12 reviews). The annual cost for participation in the IMPEP program is estimated to be \$125,280 (432 hours x \$290/hour). There is no additional recordkeeping burden associated with participation in IMPEP reviews.

AS Program Maintenance. The number of hours to maintain AS programs (expressed in full-time equivalents or FTE) varies depending on the number of licensees in the State and the scope of their Agreement (for example, some States have authority for special

programs like low-level waste or uranium recovery that would require additional FTE). The NRC estimates that it takes the average AS approximately 11.9 FTE to maintain their programs, or a total of 476 FTE annually (11.9 FTE per state for a total of 40 AS). As such, the total effort for the 40 AS is estimated to be 718,760 hours annually (476 FTE x 1,510 hours per FTE). For the purpose of this analysis, the NRC estimated that 40 percent of this burden is spent on information collection activities associated with the AS program implementation. This will constitute a total paperwork burden of 287,504 hours per year ($0.40 \times 718,760$). This estimate includes any burden associated with recordkeeping.

The NRC estimated that the average burden for each AS is 7,188 hours per year (287,504 hours per year divided by 40 ASs). The annual cost for AS program maintenance is therefore estimated to be \$83,376,160 (287,504 hours x \$290 hour).

The following summary table indicates the estimated annual burden for the information collection activities, as discussed above, required by the IMPEP questionnaire, policy statement for new ASs, participation in the IMPEP program, and maintenance of the existing AS programs. The total burden for this information collection is estimated to be 290,822 hours with a cost of \$84,338,380 (290,822 hours x \$290 hour), or an average of 7093 hours per respondent.

Description	Number of Responses	Burden Hours Per Response	Total Annual Burden Hours	Cost @\$290/hour
AS Questionnaires	12	53	636	\$184,440
New AS Applications	1	2,250	2,250	\$652,500
Participation in IMPEP Reviews	12	36	432	\$125,280
AS Program Maintenance	40	7,188	287,504	\$83,376,160
TOTAL	65		290,822	\$84,338,380

The \$290 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20, "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision Of Fee Schedules; Fee Recovery For Fiscal Year 2022 (87 FR 37214, Jun. 22, 2022).

13. Estimate of Other Additional Costs

There are no additional costs.

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses.

Based on data from the agency's time and labor reporting system, NRC staff expends approximately 8,825 staff-hours annually evaluating review information of established ASs in support of the IMPEP review program. Of these 8,598 hours, it is estimated that approximately 30 percent or a total of 2,647 hours ($0.30 \times 8,825$ hours) is expended on

information collection activities. Based upon current estimates, using the rate of \$290 per hour, the annual cost to the Federal Government is approximately \$767,630 (2,647 hours x \$290/hour).

The NRC expends approximately 7,589 staff-hours annually evaluating information submitted by established ASs in maintenance of their program. Of these 7,394 hours, the NRC estimated that approximately 25 percent or a total of 1,849 hours ($0.25 \times 7,394$ hours) is expended on information collection activities. Based on current estimates, using rate of \$290 per hour, the annual cost to the Federal Government is approximately \$536,210 (1,849 hours x \$290/hour). The NRC expends approximately 1,575 staff-hours annually evaluating a State application to become an AS. Of these 1,575 hours, it is estimated that approximately 20 percent or a total of 315 hours ($0.20 \times 1,575$ hours) is expended on information collection activities. Based upon the above noted rates, the annual cost to Federal Government is approximately \$91,350 (315 hours x \$290/hour) per application. The total annual cost to the Federal Government for one State application is approximately \$91,350 (\$91,350 multiplied by 1 State applications).

Therefore, the total annual cost to the Federal Government to review new and existing ASs is approximately \$1,395,190 (\$767,630 + \$536,210 + \$91,350).

15. Reasons for Change in Burden or Cost

There has been a decrease in the overall burden of 7,372 hours from 298,194 hours to 290,822 hours annually. The decrease is due to a change to the NRC staff's estimate on the annual burden. This is due to an evaluation of historical data on Agreement State level of effort to comply with this information collection.

Although the burden decreased, the number of FTE per Agreement State FTE for program maintenance has increased from 10.5 to 11.9 due to aligning the productive hours per FTE with current budgeting assumptions. The hours per FTE went from 1,800 hours per year to 1,510 hours per year.

In addition, the NRC staff updated the IMPEP questionnaire with the following changes; however, these changes capture activities respondents are already performing and do not affect the estimated burden to complete the questionnaire:

- Update to the wording of question 4 related vacant positions that had recently been filled.
- Items 6, 17, 25, 32 were added to clarify that the AS should provide a copy of their training, program reciprocity, licensing, inspection, and incident and allegation procedures. States were previously providing these procedures, although these items were not expressly stated in the questionnaire.
- Item 22 was added. This item requests a list of licensing actions. Most respondents were previously providing this information under item #21.
- Item 23 was added to request information on the method of record storage (electronic or paper).
- Item 28 was added to identify which version of specific guidance documents are being used by the AS. This helps the NRC to ensure that ASs are using the most recent guidance in implementing their program.
- Item 31 was added to request a list of allegations. This is a clarification. This section was titled "Incidents and Allegations" but previously did not explicitly request a list of allegations.
- Item 35 was updated to include a request for a status of outstanding comments. This is clarification a clarification of the wording and part of the standard regulations review process.
- Item 38 was added as an open-ended question to allow AS to provide additional

information, if they feel it is important or relevant to the review.

In addition, the fee rate increased from \$275 to \$290.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The NRC believes that it is impractical to put the expiration date in the Policy Statement for "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement." By supplying the expiration, the NRC would be required to republish the policy statement every time a renewal of the information collection requirements is approved by OMB. The expiration date appears on the IMPEP questionnaire.

18. Exceptions to the Certification Statement

No exceptions

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
QUESTIONNAIRE

<insert program name>
Reporting Period:

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

B. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Please provide the following organization charts, including names and positions:
 - (a) A chart showing positions from the Governor down to the Radiation Control Program Director;
 - (b) A chart showing positions of the radiation control program, including management; and
 - (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.
3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing and compliance, emergency response, low-level radioactive waste, uranium recovery, and other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program.

¹Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150 0183), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e mail: oira_submission@omb.eop.gov. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

	<u>Name</u>	<u>Position</u>	<u>Area of Effort</u>	<u>FTE%</u>
4.	Please provide a listing of all new professional personnel hired into your radioactive materials program since the last review, and if possible, who they are replacing if a recently vacated position is being filled (please indicate how long the position remained vacant). Please indicate the date of hire; the degree(s) they received, if applicable; additional training; and years of experience in health physics or other disciplines, as appropriate.			
5.	Please list all professional staff who have not yet met the qualification requirements for a radioactive materials license reviewer or inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.			
6.	Please provide copies of the Program's training procedures.			
7.	Identify any changes to your qualification and training procedure that occurred during the review period.			
8.	Please identify the technical staff that left your radioactive materials program during the review period and indicate the date they left.			
9.	List any vacant positions in your radioactive materials program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.			
10.	For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.			

II. Status of Materials Inspection Program

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| 11. | Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: license category or licensee name and license number, your inspection interval, and rationale for the difference. |
| 12. | Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800 and the number of initial inspections that were completed during each year of the review period. |
| 13. | Please submit a table, or a spreadsheet, that identifies inspections of Priority 1, 2, and 3 licensees and initial inspections that were conducted overdue. |

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Program Codes
- (4) Priority (IMC 2800)
- (5) Last inspection date or license issuance date, if initial inspection
- (6) Date Due

- (7) Date Performed
- (8) Amount of Time Overdue
- (9) Date inspection findings issued

- 14. Please submit a table or spreadsheet that identifies any Priority 1, 2, and 3 licensees-and initial inspections that are currently overdue, per IMC 2800. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection. Also include your plan for completing the overdue inspections.
- 15. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and indicate the number of reciprocity inspections of candidate licensees that were completed each year during the review period.
- 16. Please provide copies of the Program’s reciprocity procedure.

III. Technical Quality of Inspections

- 17. Please provide copies of the Program’s inspection procedure(s), or a confirmation that Program is using the NRC’s inspection procedures.
- 18. What, if any, changes were made to your written inspection procedures during the reporting period?
- 19. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

<u>Inspector</u>	<u>Supervisor</u>	<u>License Category</u>	<u>Date</u>
- 20. Describe or provide an update on your instrumentation, methods of calibration, and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

IV. Technical Quality of Licensing Actions

- 21. How many specific radioactive material licenses does your program regulate at this time?
- 22. Please provide a list of licensing actions completed during the review period, including program code, license reviewer, and license type (e.g., medical, academic, commercial, R&D, industrial radiography, gauges, etc).
- 23. Please indicate whether the licensing records are stored electronically, or in paper files, or in a combination of both.
- 24. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.
- 25. Please provide copy of the Program’s licensing procedure(s) or a confirmation that the Program is using NRC’s NUREG-1556.
- 26. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.
- 27. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

- 28. Please indicate which revision(s) of the Risk-Significant Radioactive Materials Checklist and Pre-Licensing Guidance were used by the Program during this review period.
- 29. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

V. Technical Quality of Incident and Allegation Activities

- 30. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>
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- 31. Provide a list of allegations that were closed during the review period and any allegations that remain open.
- 32. Provide copies of the Program’s Incident and Allegation procedures.
- 33. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

C. **NON-COMMON PERFORMANCE INDICATORS**

I. Legislation, Regulations, and Other Program Elements

- 34. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.
- 35. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.
- 36. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct and provide a status of any outstanding comments. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations and they have not been reviewed by NRC for compatibility, please describe their use.
- 37. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

D. **OTHER**

- 38. Is there anything else the IMPEP team should be made aware of while preparing for the IMPEP review?

II. Sealed Source and Device (SS&D) Evaluation Program

39. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sources and devices issued during the review period. The table heading should be:

<u>SS&D Registry Number</u>	<u>Manufacturer, Distributor or Custom User</u>	<u>Product Type or Use</u>	<u>Date Issued</u>	<u>Type of Action</u>
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40. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

III. Low-level Radioactive Waste Disposal Program

41. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

IV. Uranium Recovery Program

42. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

MATERIALS REQUESTED TO BE AVAILABLE FOR THE ON-SITE PORTION OF AN IMPEP REVIEW

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- List of open license cases, with date of original request, and dates of follow-up actions.
- List of licenses terminated during review period.
- Copy of current log or other document used to track licensing actions.
- List of all licensing actions completed during the review period (sorted by license reviewer, if possible).
- Copy of current log or other document used to track inspections.
- List of all inspections completed during the review period (sorted by inspector, if possible).
- List of inspection frequencies by license type.
- List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC.
- List of all licenses that your agency has imposed additional security requirements upon.

ALSO, PLEASE HAVE THE FOLLOWING DOCUMENTS AVAILABLE:

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| • All State regulations | • Documented training plan, if applicable |
| • Statutes affecting the regulatory authority of the State program | • Records of results of supervisory accompaniments of inspectors |
| • Standard license conditions | • Emergency plan and communications list |
| • Technical procedures for licensing, model licenses, review guides | • Procedures for investigating allegations |
| • SS&D review procedures, guides, and standards | • Procedures for investigating incidents |
| • Instrument calibration records | • Enforcement procedures, including procedures for escalated enforcement, severity levels, civil penalties (as applicable) |
| • Inspection procedures and guides | • Job descriptions |
| • Inspection report forms | |

