

BACKGROUND INFORMATION

ORGANIZATION OF AGREEMENT STATES MEETING

OCTOBER 1-3, 2002

Background: This “Background Information Document” was prepared for the October 1-3 Organization of Agreement States meeting by NRC and State staff to provide background information on a range of topics which are not specifically identified for discussion on the meeting agenda, but which may be of interest to Agreement State, NRC, and other meeting attendees. It is not intended to be inclusive, but is intended to provide status and background information on a number of key areas of possible interest.

During the meeting, time will be provided for meeting attendees to discuss this information. One area of discussion should be to discuss whether meeting attendees found the information useful and whether a similar background information document should be prepared for future Agreement State Meetings.

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RULEMAKING, GUIDANCE, AND PROGRAM ACTIVITIES

IMPROVING THE RULEMAKING PROCESS

The NRC formed a Rulemaking Process Improvement Task Force to review the current NRC rulemaking process and identify areas that may have potential for efficiency or effectiveness improvements. The areas of examination included the legal foundation for rulemaking, the NRC organization to implement rulemaking, the detailed steps of the process, and rulemaking data.

As part of the review process, the Task Force has been collecting stakeholder input on the process the NRC currently uses to communicate with Agreement States and with the general public during rulemakings. In May 2002, the Agreement States were sent a nine-point questionnaire covering issues including the timing and level of Agreement State involvement in NRC rulemakings, treatment of Agreement State comments, and the particulars of the commenting process. Also in May, 2002 the NRC published a Federal Register Notice posing similar questions and inviting interested parties to comment on Rulemaking Communications Improvements. In June, 2002 the NRC/OAS held a teleconference with the Agreement States to discuss these issues. The teleconference summary was posted on RADRAP. The staff has summarized the responses to the questionnaire received from representatives of ten Agreement States, and other comments in response to the FRN from five industry stakeholders. This summary will also be posted on RADRAP once finalized. The Task Force report containing any suggestions for improvement will be provided to the NRC Rulemaking Coordination Committee for their consideration in the fall.

EXEMPTIONS

The staff is considering recommendations for regulatory changes as a result of a systematic assessment of exemptions from licensing for both byproduct and source material. Revisions related to the exemptions from licensing would be included in the Part 40 rulemaking for which a rulemaking plan has been developed (discussed below, under Part 40 Review, B.). The staff is examining ways to make 10 CFR Parts 30, 31, and 32 less prescriptive and more risk-informed. A draft rulemaking plan was sent to the Agreement States for review and comment in February 2002. Comments were generally supportive with concerns about a few specific issues: (1) not fully applying recent ICRP methodology in regulations, (2) the use of the Sealed Source and Device Registry, (3) the possible exemption of general licensees from immediately reporting thefts or losses under § 20.2201(a)(i), (4) the possible NRC licensing of manufacturers for possession and use in Agreement States, and (5) not specifically requiring demonstration of ALARA in designs of products. Three Agreement States questioned NRC continued retention of authority to license exempt distribution under § 150.15(a)(6). One Agreement State suggested that a standing compatibility committee be established for this rulemaking.

PART 40 REVIEW

A. Proposed Rule - Transfers of Certain Exempt Source Materials by Specific Licensees

The NRC is proposing to amend its regulations in 10 CFR 40.51 to require Commission approval for transfers of unimportant quantities of source material (less than 0.05 percent by weight) to persons exempt from licensing requirements. The object of this proposed action is to

ensure that transfers of materials containing low concentrations of source material are adequate to protect public health and safety. The proposed action also amends 10 CFR 40.13(a) to clarify that disposal of unimportant quantities of source material is exempted.

The proposed rule was published in the Federal Register [67 FR 55175] on August 28, 2002, and the comment period is scheduled to end on November 12, 2002.

B. Rulemaking Plan - Distribution of Source Material to Exempt Persons and to General Licensees and Revision of the 10 CFR 40.22 General License

The NRC staff has developed a rulemaking plan to address the distribution of source material to persons exempt from licensing and to general licensees, in a manner intended to make Part 40 in Title 10 of the Code of Federal Regulations (CFR) more risk-informed. The draft proposed rulemaking plan provides options to revise 10 CFR Part 40.

The rulemaking plan was submitted to the Commission for consideration.

C. Part 40 Jurisdictional Working Group

The Commission directed the staff to work with the States and other federal agencies to identify regulatory options to assure protection of public health and safety from risks associated with materials containing low concentrations of uranium and/or thorium and their decay products. The Working Group has met several times in 2001 and 2002, and an update of the Working Group's progress was sent to the Commissioners on August 13, 2002. The staff considered the assessment in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" (published in June 2001), and does not believe that there is a significant health and safety problem that warrants urgent regulatory action by NRC. As a result of the Working Group efforts, the staff is considering an approach to limit NRC authority to uranium and thorium that are purposely extracted or used. Next steps will include drafting a Commission paper in which the staff will make recommendations for the best approach for delineating responsibilities related to low-level source material.

The web site for the Part 40 Jurisdictional Working Group is:

<http://www.nrc.gov/materials/src-materials-facilities/jurisdictional.html>

ENTOMBMENT ISSUES FOR DECOMMISSIONING

NRC published an Advance Notice of Proposed Rulemaking on October 16, 2001 (66 FR 52551) seeking stakeholder input on whether entombment was a viable decommissioning alternative. The ANPR comment period closed on December 31, 2001. NRC received 19 comments from: six States; eight licensees; the Nuclear Energy Institute (NEI); the U.S. Environmental Protection Agency (EPA); the Conference of Radiation Control Program Directors' E-24 Committee on Decommissioning and Decontamination (CRCPD E-24 Committee); the Southeast Compact Commission (SCC); and a private individual.

Generally, the eight utilities and NEI stated that they would like to have entombment available as a decommissioning option; however, none unequivocally committed to using entombment in their

decommissioning process. Some Agreement State commenters also endorsed the Part 20 dose limits, with one State adding that a time limit to reach the dose rates should be considered. One State advocated extending the decommissioning period beyond 60 years, but most were silent on the decommissioning regulations in Part 50. The staff notes that there was no consensus on a preferred option. NRC staff carefully considered the comments received and is preparing a paper transmitting the Staff's recommendations to the Commission. A draft of this paper was posted on the Technical Conferencing Forum for State comment. Comments were requested by September 30, 2002.

PORTABLE GAUGES RULE

In an effort to improve the control of radioactive materials, the staff is considering regulatory changes to prevent, deter, and/or detect thefts of portable gauges. An NRC/Agreement State Working Group has been established to analyze the root causes and to evaluate various options for reducing the number of thefts. A rulemaking plan will not be prepared for this rulemaking. Instead, the working group will recommend a preferred option for management approval prior to drafting the proposed rule.

MEDICAL USE OF SEALED SOURCE DEVICES-UNDER THE NEW PART 35 & THE SS&D REGISTRY

The new Part 35 directs licensees to use sealed sources for manual brachytherapy (35.400); diagnosis (35.500); and photon emitting remote afterloaders, teletherapy units and gamma stereotactic radiosurgery units (35.600) as approved in the Sealed Source Device Registry. The intent is to have the SS&D registration provide any limitations in the approved use of the source. Supplemental information has been prepared to address the use of sources in the SS&D Registry that were reviewed before the new Part 35 and have only a general medical use listed in the "category" description.

DECOMMISSIONING GUIDANCE CONSOLIDATION

In 2001 the staff initiated a decommissioning guidance consolidation project. The project involves review and consolidation of all existing NMSS decommissioning guidance documents, decommissioning technical assistance requests, decommissioning licensing conditions, and all decommissioning generic communications issued over the past several years. The goal is to produce consolidated NMSS decommissioning guidance that allows the NRC staff to evaluate information submitted by licensees in a timely, efficient, and consistent manner that protects public health and safety. The end result will be a streamlined multi-volume NUREG grouped into decommissioning functional categories. Further ease of use will be realized by making this a web-based document.

The project team began developing the first NUREG volume (Decommissioning Procedures) in June 2001, and has issued Volumes 1 and 2 (Dose Modeling) for public comment. Volume 1 was issued as a final guidance in September 2002. The overall project is scheduled to be completed by the end of FY2003. The updated, consolidated guidance will be provided to all users, both NRC and licensee in hard-copy and/or electronic media. Since each group will have access to the same guidance, the expected results are more complete license documents that will expedite the

approval process for both applicants and reviewers. As a result, it is expected that this project will serve to improve the overall decommissioning process.

In concert with this guidance consolidation project, the Nuclear Energy Institute (NEI) and the NRC staff identified an approach to clarify existing guidance associated with the License Termination Rule (10 CFR 20, Subpart E). NEI's License Termination Task Force (Task Force) generated questions (Qs) associated with decommissioning issues that are common to the industry. The Task Force also proposed answers (As) to the questions and NRC staff reviewed the Q&As. The NRC staff and the Task Force further developed the Q&As so that they adequately reflect NRC regulations and guidance and include a sound technical basis. This joint Q&As initiative was discussed at the June 1, 2002, public workshop on the guidance consolidation project. As a result of this cooperation, seven Q&As have been found acceptable by the NRC staff and are provided in an appendix to Volume 2 of NUREG-1757. The NRC staff and the Task Force are continuing work on additional questions, which will be published separately.

COMPATIBILITY WITH IAEA TRANSPORTATION STANDARDS ISSUES

A proposed rule to revise 10 CFR Part 71 has been published in the Federal Register for public comment on April 29, 2002 (67 FR 21390). This rule will make Part 71 compatible with the IAEA transportation safety standards TS-R-1, and promulgate other NRC-initiated transportation safety amendments. The staff used the enhanced-public process to solicit input and comment from the public on the proposed rule, including holding 2 public meetings. The first meeting was held in Chicago on June 4, 2002, and the second held on June 24, 2002 in the NRC TWFN Auditorium. The public comment period ended on July 29, 2002. A total of 166 comments were received to-date.

NRC/OAS WORKING GROUP STATUS

NRC and the Agreement States continue to address policy and rulemaking issues using NRC/State Working Groups. A list of currently active working groups is attached. Information on the status of the IMC 2800 and two person rule working groups follows.

Revision of IMC 2800 and Associated IP

In April 2002, the NRC and the Agreement States cooperated through a joint working group to initiate a 12-month pilot program to revise administrative processes described in Inspection Manual Chapter 2800, Materials Inspection Program (IMC 2800) by: (1) using risk insights to set inspection priorities, (2) empowering inspectors, (3) streamlining processes for initial inspections and field office inspections, and (4) streamlining inspector preparation and documentation of routine inspections.

This initiative was identified as "Project 5" in SECY 02-074 (Policy Issue Information), "National Materials Program: Pilot Projects," dated May 3, 2002. In its Staff Requirements Memorandum dated August 20, 2002, for SECY 02-107, "Addendum to SECY 02-074," the Commission supported the staff to continue with current activities to pilot test and evaluate revised IMC 2800 and its associated routine inspection procedures (IP 87110 series). Based on the pilot, the staff will identify lessons learned and experience to help understand the effectiveness and efficiency gained to finalize the revised IMC 2800 and IP 87110 series.

Evaluation of Two Person Rule

In June 2002, the NRC and the Agreement States initiated a joint working group to evaluate the impact the two person rule (10 CFR 34.41) has had on the health and safety of industrial radiography workers and members of the public since the effective date of the rule on June 27, 1998. The final report will address the efficacy of the current rule and recommend a preferred implementation strategy or rule change, which, in the staff's view, will most effectively and efficiently meet the stated objectives of the two-person rule, i.e., to enhance the level of protection of radiographers (by providing immediate assistance when needed) and the public (by preventing unauthorized entry into the restricted area) during radiographic operations.

The staff is considering the development, interpretation, and implementation of the existing rule. A risk-informed approach is being used to review information about events that involved two-person radiography crews over the last four years. The staff is obtaining information from the Agreement States. The final report will be completed in fall 2002.

Working Group Reports

Since the 2001 OAS Annual Meeting, two working groups have issued final reports. The Integrated Materials Performance Evaluation Program (IMPEP) Lessons Learned Working Group final report, dated April 1, 2002, contains a number of recommended improvements to the IMPEP process. NRC staff is taking action to address many of the recommendations including preparation of a "follow-up IMPEP review" procedure and revising the periodic meeting process.

The Final Report of the Working Group On Uranium Milling License Termination in Agreement States was issued July 2002. The final report includes a draft revised Procedure SA-900, "Termination of Uranium Milling Licenses in Agreement States," that addresses issues identified by the Working Group and stakeholders. The draft revised procedure will be published shortly for broader Agreement States and stakeholders comment before it is issued in final.

In addition, a revision to Management Directive 5.3, NRC/Agreement State Working Groups, was issued July 24, 2002, following Agreement State review and comment. The revision better defines the roles and responsibilities of both NRC and Agreement State staff in the establishment and implementation of working groups. New features include information that must be included in a working group's charter, the role of a steering committees, and a description of the role of a new NRC/Agreement State Working Group Coordinator.

NRC AND EPA MEMORANDUM OF UNDERSTANDING

NRC and the Environmental Protection Agency (EPA) have been developing a Memorandum of Understanding (MOU) on decommissioning and decontamination of contaminated sites. The EPA and NRC, in recognition of their mutual commitment to protect the public health and safety and the environment, entered into an MOU in response to Congressional direction and in order to establish a basic framework for the relationship of the agencies in the radiological decommissioning and decontamination of NRC-licensed sites. The MOU is intended to address issues related to the EPA involvement under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) in the cleanup of radiologically contaminated sites

under the jurisdiction of the NRC. The NRC License Termination Rule published in 1997 is not changed by this MOU. Similarly, the EPA will continue its CERCLA policy of September 8, 1983, which explains how EPA implements deferral decisions regarding listing on the NPL of any sites that are subject to NRC's licensing authority.

NEW WEB SITE FOR STATE ALLEGATIONS

In response to suggestions from the Agreement States on reporting of Agreement State allegations and concerns, staff has developed a separate web site area on the NRC web site which discusses the reporting of concerns involving States and Agreement States. The web site is located at: <http://www.hsr.d.gov/nrc/allegations.htm>.

A visitor to the NRC web site, wishing to report a safety or security concern would go to the area labeled "Report a Safety or Security Concern." Under the section "Non-Emergency," individuals interested in reporting a safety or security concern are invited to learn more about non-emergency concerns involving States and Agreement States. When this topic is clicked, web site visitors are taken to the site "Non-Emergency Concerns Involving States and Agreement States." This site is divided into two general topics: State Program Concerns and Agreement State Program Concerns. The State Program Concerns section explains that there are some sources of radiation not regulated by the NRC and provides information for persons to contact the State directly regarding these concerns. The Agreement State Program Concerns section explains the Agreement State Program and identifies the Agreement States. This section also provides information on the ability of the State to protect alleged's identity from public release and provides information for persons to contact the Agreement State directly with regard to their concerns.

GRANT PROGRAM FOR NRC FORMERLY LICENSED SITES IN AGREEMENT STATES

NRC's grant program for financial assistance to support Agreement States in closing outstanding sites formerly licensed by the NRC was announced through a Federal Register Notice (66 FR 8814) published in February 2001. The grant program is organized into four areas for funding assistance: (1) proposal for file reviews and/or initial surveys, (2) proposal for regulatory oversight for site characterization and/or remediation, (3) proposal for site characterization, and (4) proposal for site remediation. Each State that desires funding assistance is required to submit a written grant proposal to NRC for review and approval.

There were nine Agreement States that were eligible for funding assistance: Arizona, California, Colorado, Massachusetts, North Dakota, New Mexico, New York, Texas and Utah. Grant proposals for file reviews and/or initial surveys have been reviewed and awarded to Arizona, California, Colorado, Massachusetts and Texas. Arizona, and Texas have completed grant project work and closed all files. Colorado has closed all files except for one site that has been found contaminated. Colorado is preparing a site characterization proposal for this site. Three contaminated sites in California are under remediation by the former licensee or current site owner. California is also preparing a regulatory oversight proposal for these sites and is continuing file reviews and site surveys for other sites. North Dakota and New Mexico have closed all site files. All sealed source files in New York are closed. New York is completing a grant proposal for remaining loose material sites. Utah indicated that they will review formerly licensed site files but will not request funding assistance.

The grant program began in the FY 2001 and is expected to be completed by the end of FY 2004. The total funding available for the program is \$3.3M.

STATUS OF AGREEMENT STATE NEGOTIATIONS

Currently three States are negotiating Agreements. Wisconsin submitted a final application on September 21, 2002. Minnesota submitted a draft application for a completeness review on July 13, 2002. NRC staff provided comments to Minnesota on the draft application on September 12, 2002. Pennsylvania Agreement has been extended at the Commonwealth's request. In addition, staff has completed a review of Utah's draft application to assume uranium mill tailings authority. One issue identified during the review was differences in Utah and NRC groundwater protection regulations. This issue is being further analyzed by Utah and NRC Staff. The following status summaries were prepared and provided by State staff

Pennsylvania

A draft of the application was submitted to NRC in 1999 for a completeness review.

The Pennsylvania regulations for Radiological Health were revised for compatibility. Following approval by the Radiation Protection Advisory Committee, the Environmental Quality Board and the Independent Regulatory Review Committee, the revised regulations went into effect in the fall of 2001. The regulations incorporated the necessary parts of 10 CFR by reference and made them applicable to x-ray registrants as well as NARM licensees. The licensing fee structure was revised along NRC license categories to accommodate assimilation of the NRC licenses and assure adequate funding.

The NRC sent a letter to Secretary of the Department, David Hess, in the fall of 2001 requesting an update on Pennsylvania's progress with the application. The response was that submission of the application was expected early in 2003.

There are two issues which have had the greatest impact on progress. The first is the potential impact of the assumption of legacy liabilities. NRC has several SDMP projects ongoing and a couple of active licensees with substantial decommissioning liabilities. These issues are being worked out. The second problem is staffing. A request to add 20 new positions for the program was submitted in the summer of 2001 and has not been approved. The request for additional staff will be resubmitted in the fall of 2002. The director of the Bureau of Radiation Protection has been temporarily reassigned to the position of Deputy Secretary over Air and Radiation Protection. That may positively influence the outcome.

In the meantime, technical staff continue to receive the necessary training without problem and the licensing and inspection infrastructure system is being enhanced at the procedural and hardware levels. That part will go forward to support the existing NARM program regardless of the status of the application.

Minnesota

The Governor, with the Minnesota Department of Health as the lead agency, was granted authority under 1998 Minnesota Laws, chapter 407, to pursue Agreement State status with the

U.S. Nuclear Regulatory Commission. Among unique features of the state law are passages that (1) set a "final completion" deadline of August 2, 2003, by which the federal government must approve the application or any rules adopted for this program are repealed, and (2) the final agreement must be approved by law before it may be implemented.

The draft application was submitted to NRC in July 2002 and the Radiation Control Unit staff is responding to NRC completeness review comments in completing a final application. In the meantime, rulemaking is proceeding on the state level and staff are taking required training. Staff for the radioactive materials licensing program include some current x-ray inspectors who have expressed a desire to assist in this new program. The x-ray inspectors positions will be filled behind these staff once the program is approved.

The Radiation Control unit will conduct a series of workshops for material users to inform of changes and to alleviate the transition to new rules.

Wisconsin

The State of Wisconsin officially declared its intent to pursue Agreement State status in September, 1998. Prior to this, the Wisconsin Radiation Protection Section (RPS) developed a very detailed management and funding plan for becoming an Agreement State that continues to guide its efforts. The process of and the focus on becoming an Agreement State has helped to re-energize existing staff and added seven (7) new staff that are combining to form a positive, goal oriented program. At present, the status of Wisconsin's development effort is as follows:

1. The RPS has completed the necessary statutory and rule upgrades needed to meet NRC requirements.
2. The new materials program is fully staffed.
3. Staff are actively attending NRC training courses, accompanying NRC inspectors during inspections and performing 'program reviews' (inspections) of Wisconsin NARM users currently under state jurisdiction.
4. The state submitted the draft Agreement State application to the NRC in June, 2002.
5. The state submitted the final Agreement State application on September 21, 2002.
6. The RPS is planning a series of statewide, one-day workshops during October or November, 2002 for all material users to discuss the Agreement State transition process and the new radiation protection rule.

Wisconsin hopes to become an Agreement State by July, 2003.

THE NATIONAL MATERIALS PROGRAM

References:

-SECY-01-0112 "National Materials Program: Transmittal of Final Working group Report Presenting Options for a National Materials Program;"

-SECY-02-0107 "National Materials Program: Pilot Projects;" and

-SECY-02-074 "Addendum to SECY-02-0074 "National Materials Program: Pilot Projects."

-Staff Requirements memorandum for SECY-01-0112, SECY-02-0107, and Addendum to SECY-02-0107.

NRC, CRCPD, and OAS Board staff have continued work on the pilot projects. Responsibility has been assigned for each of the five pilot projects whereby each organization, and an existing working group, will take the lead for one pilot project, as follows:

Project 1 - Involve Agreement States in establishing priorities for development of materials policy, rulemaking, and guidance products in the materials and waste arenas. (STP Lead)

Project 2 - Agreement State/CRCPD assumes lead for national radiographer certification program. (CRCPD Lead)

Project 3 - Agreement States participate in joint process with NRC to evaluate NRC and Agreement State events for possible generic implications and possible regulatory action. (NMSS Lead)

Project 4 - Agreement States assume responsibility for development of licensing and inspection guidance for a new use of material, or new modality, not previously reviewed and approved. (OAS Lead)

Project 5 - NRC and the Agreement States work cooperatively through a joint working group to address implementation of specific Phase II recommendations. (Lead is being assigned to the Existing Phase II Implementation Working Group.)

Except for Pilot Project 5, which has an existing charter, NRC, CRCPD and OAS agreed that the lead organization would draft a charter for their assigned pilot project for discussion at the October OAS meeting. (Copies Attached.) The charter provides information on work to be accomplished, level of effort and types of staff expertise needed. Agreement State representatives are needed for the first four Pilot Projects. The Commission has asked for a report on the results of the pilot projects by November 2003.

RISK-INFORMING INITIATIVE IN THE MATERIALS AND WASTE ARENAS

The risk-informing initiative, described and approved by the Commission in SECY-99-100, is designed to identify and assess risks associated with a diversity of regulated activities, and prioritize and allocate resources appropriately. Through several case studies, the staff has established screening considerations for identifying regulatory activities that could benefit from a more risk-informed approach and developed working draft safety goals. A public meeting will be held in 2003 to solicit input on the safety goals for the materials and waste arenas.

As part of this initiative, a three-tiered training system for administrative, managerial, and technical staff was instituted. Of particular interest are the "Introduction to Risk Assessment in NMSS (P-400)" and "Byproduct Materials System of Risk Analysis and Evaluation in NMSS (P-405)" courses. P-400 introduces the risk assessment concepts and the various risk analysis approaches used for materials safety and waste safety applications. P-405 provides a general understanding of the process of developing risk analysis to populate the underlying database of NUREG/CR 6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems." It is expected that these courses will be opened to State personnel.

THE CONSIDERATION OF POTASSIUM IODIDE IN EMERGENCY PLANNING

The Nuclear Regulatory Commission has revised a section of its emergency preparedness regulations. The revised rule requires that States and Native American governments with a population within the 10-mile emergency planning zone of commercial nuclear power plants consider including potassium iodide as a protective measure for the general public to supplement sheltering and evacuation in the unlikely event of a severe nuclear power plant accident.

The final rule amends 10CFR50.47(b)(10). The NRC published the rule change in the Federal Register (Volume 66, Number 13, page 5427) on January 19, 2001. The change became effective April 19, 2001.

Along with this rule change, the NRC is providing funding for a supply of potassium iodide for a State that chooses to incorporate potassium iodide for the general public into their emergency plans. After funding the initial supply of potassium iodide, the Commission may consider extending this program to fund replenishment supplies, but has made no commitments in this regard.

The NRC and the Federal Emergency Management Agency (FEMA) are the two Federal agencies responsible for evaluating emergency preparedness at and around nuclear power plants. The NRC is responsible for assessing the adequacy of onsite emergency plans developed by the utility, while FEMA is responsible for assessing the adequacy of offsite emergency planning. The NRC relies on FEMA's findings in determining that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Eligibility for Obtaining Potassium Iodide

This rule applies to States and Tribal governments with Nuclear Power Plants within their borders, with populations within the 10-mile emergency planning zone, and local governments designated by States to request potassium iodide funding.

The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's supply of potassium iodide strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of potassium iodide and acknowledging the offsite authorities' role in such matters. By requiring consideration of the use of potassium iodide, the Commission recognizes the important role of States and local governments in matters of emergency planning.

Process for Obtaining Potassium Iodide

On December 20, 2001, the NRC sent letters to the 34 States with populations within the 10 mile emergency planning zone of nuclear reactors. This letter discusses the NRC program to provide potassium iodide to states and includes, as attachments; the NRC Statements of Consideration in support of the final rule; the Food and Drug Administration (FDA) final guidelines on use of potassium iodide, FEMA guidelines on incorporating potassium iodide into emergency response plans as well as the NRC disclaimer .

The revised Federal Policy on Use of Potassium Iodide (FR Volume 67, Number 7, page 1355) was also provided to the States.

The Office of Public Affairs issued a press release on December 20, 2001, to announce the NRC's potassium iodide program.

Regulations and Guidance

The NRC final rule on the Consideration of Potassium Iodide in Emergency Plans was published in the Federal Register Notice on January 19, 2001. This rule became effective April 19, 2001. The FDA final guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies was published in December, 2001. The Federal Emergency Management Agency published the revised Federal Policy on the Use of Potassium Iodide in January 2002.

Current Status

As of September 5, 2002, sixteen states; Massachusetts, Connecticut, Maryland, Vermont, Delaware, Florida, Alabama, Arizona, New York, New Jersey, North Carolina, Pennsylvania, California, Ohio, Virginia, and New Hampshire have requested and received potassium iodide tablets.

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**CURRENTLY ACTIVE
NRC/AGREEMENT STATE WORKING GROUPS
SEPTEMBER 2002**

General	
<p>Re-Evaluation of the Two Person Rule Thomas Young, NRC NMSS J. Bruce Carrico, NRC NMSS Kim Karcagi, NRC NMSS James Smith, NRC NMSS Mark Shaffer, NRC RIV Sally Merchant, NRC OE Maria Schwartz, NRC OGC James Myers, NRC STP Jan Endahl, Texas</p>	<p>Revision to IMC 2800 Thomas Young, NRC NMSS, Chair Anita Turner, NRC NMSS James Smith, NRC NMSS Richard Blanton, NRC STP John McGrath, NRC RI John Pelchat, NRC RII Jamnes Cameron, NRC RIII Michael Fuller, NRC RIV Robert Gallagher, Massachusetts</p>
<p>American Society for Nondestructive Testing, Industrial Radiography Certification Process Bruce Carrico, NRC NMSS, Chair Jan Endahl, State of Texas Charles Gutzman, State of Illinois George Johns, State of Iowa James Myers, NRC STP</p>	<p>Radiography Associated Equipment 10 CFR 34.20 Thomas Young, NRC NMSS, Chair Jim Myers, NRC STP Maria Schwartz, NRC OGC Bruce Carrico, NRC NMSS/MSIB Deborah Piskura, NRC RIII Dave King, South Carolina Salifu Dakubu, Massachusetts William Hutchenson, Ohio Michele Burgess, NRC NMSS, Resource</p>

10 CFR 40.13(a) and 40.20 Working Groups

<p>Jurisdiction/Source Material Torre Taylor, NRC NMSS, Chair Cathy Mattsen, NRC NMSS Gary Comfort, NRC NMSS Kristina Banovac, NRC NMSS Maria Schwartz, NRC OGC Dennis Sollenberger, NRC STP Ken Weaver, Colorado Loren Setlow, EPA Hal Peterson, DOE Fred Ferate, DOT Brian Hearty, USACE Chia Chen, OSHA Nick Reager, BLM Adam Klinger (backup), EPA Alexander Williams (backup), DOE Richard Wright (backup), DOD</p>	<p>Part 40 Rulemaking Activity Gary Comfort, NRC NMSS, Chair Catherine Mattsen, NRC NMSS Mike Fliegel, NRC NMSS Jean-Claude Dehmel, NRC NMSS Elizabeth Ullrich, NRC RI Maria Schwartz, NRC OGC Kevin Hsueh, NRC STP Bill Sinclair, Utah Steve Collins, Illinois</p>
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Control of Solid Materials

<p>Working Group Frank Cardile, NRC NMSS, Chair Bob Meck, NRC RES Anthony Huffert, NRC NMSS Osiris Siurano, NRC STP Patricia Holahan, NRC NMSS Steve Klementowicz, NRC NRR Elaine Brummet, NRC NMSS George Powers, NRC RES Giorgio Gnugnoli, NRC NMSS/DWM Audrey Hayes, NRC NRR Rosemary Hogan, NRC RES Kathryn Barber, NRC OGC Peter Myers, Texas</p>	<p>Steering Committee Don Cool, NRC NMSS William Reamer, NRC NMSS Cheryl Trottier, NRC RES Stuart Treby, NRC OGC Ted Quay, NRC NRR Paul Lohaus, NRC STP Steve Collins, Illinois</p>
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**Decommissioning Guidance Consolidation Working Groups
Jack Parrott, NRC NMSS, Coordinator**

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Proposed Charter Pilot Project #1

Background

The National Materials Program (NMP) is a term that defines a collective framework within which the NRC and the Agreement States work together to maintain and carry out their respective materials radiation control programs. This framework also includes the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD). The NMP outlines the day-to-day activities carried out by a materials regulatory program, such as licensing and inspection, and the additional responsibilities shared by each program to help maintain an adequate national base of rules and guidance needed for effective program operation. The Alliance Option, as identified in SECY-02-0074, reflects a continuation of current NRC and Agreement State programs. However, work to develop national regulatory products (rules and guidance) and priorities for those products are performed in a collaborative manner. This pilot is intended to help examine and determine how NRC and States can collaborate in the identification of regulatory priorities, corresponding work products, and responsibility for those work products.

Objectives

1. Help establish a process and understanding on how NRC and Agreement States can collaborate in the identification of work products and establishment of priorities for products needed in the materials program.
2. Help demonstrate NRC's willingness to involve Agreement States to ensure that State needs are known and considered along with those identified by NRC staff in the establishment of national priorities for materials program work.
3. Help demonstrate the willingness and process which the Agreement States could use to establish a collective position on national needs and priorities for the materials program.
4. Help demonstrate how decisions on implementing plans for materials program work could be shared by NRC and individual Agreement States (e.g. how NRC and the Agreement States could reach agreement on respective responsibilities for completion of work products identified in a national priority list).

Scope of Work

1. Obtain information and develop understanding of the process utilized by NRC to establish work priorities for the materials program.

2. Define a process which the Agreement States could use to identify State materials priorities and a collective view or position on those priorities.
3. Examine and identify points in NRC's process where States can participate and provide input in the establishment of priorities for development of materials policy, rulemaking, and guidance products.
4. Examine and identify whether a different process could be utilized by NRC and the States in the establishment of priorities for development of materials policy, rulemaking, and guidance products.
5. Examine processes which NRC and the Agreement States could use to make decisions on implementing plans for materials program work and how that work would be shared by NRC and individual Agreement States (e.g. Examine ways that NRC and the Agreement States could reach agreement on respective responsibilities for completion of work products identified in a national priority list).

Organization and Operations

Work under this pilot would be carried out by a working group consisting of NRC staff, and State staff selected by the OAS and CRCPD Boards. A proposed composition of the working group would include staff from:

- Division of Industrial Medical and Nuclear Safety/NMSS
- Program Management, Policy Development and Analysis/NMSS
- STP
- OAS -Office of Chief Financial Officer/NRC Representative(s)
- CRCPD Representative(s)

Schedule

A schedule will be developed by the Working Group to meet the Commission's November, 2003 report date.

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National Materials Program Pilot Project National Industrial Radiographer Certification Program Charter

Objective

The Conference of Radiation Control Program Directors, Inc. (CRCPD), through its G-34 Committee on Industrial Radiography will serve as the lead organization for the oversight of all activities associated with a national industrial radiographer certification program. This includes the review and approval of state government and independent certifying entities' initial applications for approval as recognized certifying entities and subsequent program changes, and follow up evaluations of program status, including test administration and program maintenance activities.

The initial committee action will be to formalize the criteria and process in a CRCPD document for reviewing and approving requests to be recognized as certifying entities, through consistent application of criteria that reflect nationally-accepted standards, e.g. for radioactive materials only - 10 Code of Federal Regulations, Part 34, Appendix A; and the equivalent CRCPD document for x-ray only and combination certifications. The document will also include proposed strategies for accomplishing the follow-up program evaluations at predetermined intervals after recognition as a certifying entity is granted.

Step two will be to apply the process for obtaining approval as a certifying entity, including the initial approval or subsequent program changes. The committee will implement the actual mechanics of the sequence of events for initial approval or subsequent program changes.

Work Product(s)

Work Product One is the CRCPD document that contains the formalized criteria and process for reviewing and approving an initial request to be recognized as a certifying entity, subsequent program changes, and proposed strategies for follow-up program evaluations after recognition as a certifying entity is granted.

Work Product Two is a documented evaluation of the application of the criteria and process established in the CRCPD document described as Work Product One. Due to time constraints, the follow-up evaluation of program activities proposed in the document will not be a part of this pilot. The pilot will be applied to either Option One or Option Two as described below, depending on which opportunity presents itself.

Option One: If presented, the committee will review the application of a potential certifying entity's program. The application could be an initial application or a program's proposed change. The committee will provide an evaluation of its review of the application against the application process and formalized criteria.

Option Two: If a new application or a program change is not presented for review, then the committee will review the process previously used in evaluating the American Society for Nondestructive Testing's application for approval of its x-ray and combination certification programs, and provide an evaluation of that review process.

Schedule

Formalization of the criteria and process for reviewing applications or program changes, and documentation of the proposed strategies for follow-up program evaluation will be completed by March 31, 2003.

Review of a new application or program change and evaluation of the process will be completed by December 31, 2003.

If no new application or program change is presented for review and approval, the evaluation of the process previously used for reviewing ASNT's application will be completed by October 31, 2003.

Estimated Resources

The program will involve the participation of the three state representatives who serve on the G-34 Committee, and one federal representative who serves as the NRC resource person to the G-34 Committee. The hours stated are per person. A representative from the industrial radiography industry will be invited to participate, but participation will be at industry expense.

Formalize the evaluation criteria and process, and strategies for follow-up evaluation:

12 hours - initial face to face meeting (travel time not included)
 12 hours - telephone conference calls to formalize
4 hours - write up
 28 hours

Option One:

Review of new application or proposed program change:

12 hours - initial face to face meeting (travel time not included)
 24 hours - telephone conference calls
4 hours - write up
 40 hours

Option Two:

Evaluation of the process previously used:

12 hours - initial face-to-face meeting (travel time not included)
 6 hours - telephone conference calls
4 hours - write up
 22 hours



PROPOSED CHARTER
Pilot Project #3: Event Evaluation
July 24, 2002

Background

On May 3, 2002, the Commission was informed of five pilot projects (SECY-02-0074) the staff is undertaking; in coordination with the Agreement States, to provide additional information to help understand the feasibility and viability of the Alliance Option recommended by the National Materials Program Working Group.

The Alliance Option reflects a continuation of current NRC and Agreement State programs, but work to develop national regulatory products (rules and guidance) and priorities for those products performed in a collaborative manner. Decisions are based on a participatory process between NRC and the Agreement States, in which the Agreement States assume greater responsibility for devoting resources to development of regulatory products.

NRC Staff, the OAS Executive Board, and State members of the CRCPD Board of Directors collaborated in the identification of the five pilot projects which can be readily implemented, and which will help provide additional information on how the States and NRC might operate with an Alliance type program structure. The pilots can be implemented without significant resource impacts on NRC programs.

Objectives

In the implementation of one of the five pilot projects, the Working Group (WG) is chartered to develop criteria that would enable Agreement States to assume the lead role for the evaluation of events occurring in individual Agreement States for generic implications and possible regulatory action.

The WG will incorporate a two-phased approach in the implementation of the pilot. The first phase will be to achieve goals in a limited area and to develop lessons learned as a collective effort in event evaluation, using the NMSS Policy and Procedures Letter (P&PL) 1-57, "Generic Assessment Process" as a basis for event evaluation. The WG will focus on radiography overexposures as a case study for event review and will perform an assessment of radiography events for generic implications. The WG will evaluate the assessment of radiography events for possible regulatory actions. The costs associated with the Agreement States assuming the lead role for event evaluation will also be analyzed by the WG. Lessons learned as well as recommendations on the event evaluation process will be documented by the WG.

The second phase will be for the WG to utilize the experience of the first phase to identify other areas for event evaluation implementation. The revised process will be implemented using the newly identified area for event review and assessment for generic implications. The WG will document the lessons learned as well as general recommendations on the revised event evaluation process.

NRC management will assess results of the pilot against standard agency actions related to event evaluation.

Scope of Work

WG efforts include the following two-phased approach:

Phase I

1) Review NMSS Policy and Procedures Letter (P&PL) 1-57, "Generic Assessment Process" for potential State involvement. Currently, IMNS has the lead responsibility for coordinating the generic assessment process for NMSS.

2) Perform quarterly reviews in NMED using radiography events as a basis for evaluation. Events should be reviewed to identify trends or frequency of occurrence through analysis of cumulative event data.

3) Evaluate the event evaluation process for the identification of possible regulatory actions in response to performance trends.

4) Evaluate the costs of Implementing Agreement States as lead for event evaluation.

5) Provide general recommendations/ lessons learned on the event evaluation process.

Possible Outcomes

a) Revision of P&PL 1 -57 procedure

b) Transfer of event evaluation function from NRC to Agreement States

c) Parallel event evaluation function between NRC and Agreement States

6) Provide documentation of revised process in report form for review by NRC management.

Phase II

1) Identify other areas for event evaluation.

2) Implement revised event process using the newly identified area.

3) Document lessons learned/recommendations of revised process.

The output of this pilot will be in a report form and will be reviewed by NRC management for assignment of actions via an implementation plan.

Organization and Operations

The Working Group will consist of one member from IMNS, and one member each from the two participating states, preferably Texas and Louisiana. IMNS will serve as a monitor in the implementation of this pilot. The organization and operation will accomplish the objectives set forth above within the schedule indicated below.

Schedule

August 2002

December 2002

March 2003

Solicitation of Working Group Members

Phase I

Phase II

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PROPOSED CHARTER

"Project 4 - Assumption of responsibility for development of guidance for new use or modality not previously reviewed and approved"

Purpose

To develop an implementation strategy for pilot project #4 defined in SECY-02-0074. This pilot project will better define the feasibility and viability of the Alliance Option recommendation by the National Materials Program Working Group. This pilot project is to be implemented by the Organization of Agreement States (OAS).

Background

The National Materials Program (NMP) is a term developed to define the broad collective framework within which both the NRC and the Agreement States function in carrying out their respective radioactive materials regulatory programs. Such a framework also includes the OAS and the Conference of Radiation Control Program Directors, Inc. (CRCPD). The NMP defines the day-to-day activities carried out by a radioactive materials regulatory program, such as licensing and inspection activities. It also defines responsibilities shared by federal and state programs to help maintain an adequate national base of rules and guidance needed for effective program operation. The Alliance Option was one of the options examined by the NMP Working Group (see SECY-01-0112). The Alliance Option reflects a continuation of current NRC and Agreement State programs, but tasks to develop national regulatory products (e.g., rules and guidance) and priorities for such products are performed in a collaborative manner. Decisions are based on a participatory and collegial process between NRC and the Agreement States, and the Agreement States may assume greater responsibility for devoting resources to development of regulatory products.

Scope of Work

Under this pilot project an Agreement State, groups of Agreement States, or individual experts within the Agreement States assume responsibility for development of licensing and inspection guidance for a new use of material, or new modality, not previously reviewed and approved.

Objectives

1. Survey the Agreement States, NRC Headquarters, and the NRC Regions to ascertain if there is a new use of material or new modality that would qualify under this pilot project. This survey

would be accomplished during the annual meeting of the Organization of Agreement States scheduled for October 1- 3, 2002 in Denver, Colorado. Prior to the meeting, an announcement of the survey and desired objectives would be relayed to the Agreement States/NRC via RADRAP. The survey should also reflect the desire of an Agreement States, groups of Agreement States, or individual experts within the Agreement States to work together to develop a regulatory product (sealed source and device registry sheet, inspection and/or licensing guidance). The survey will be provided in written form at the commencement of the meeting and a time scheduled during the meeting to share and discuss the results of the survey.

2. If a new use of material or new modality is identified as a result of the survey at the OAS annual meeting, the OAS Executive Board will determine which new use of material or new modality inspection and licensing guidance will be developed and who will be the lead Agreement State, groups of Agreement States, or individual experts within the Agreement States for development of such guidance and facilitation of the process. For example, it may be best to allow the state regulatory agency having jurisdiction over a manufacturer of a new device or product develop the licensing and inspection guidance which reviewers should apply in reviewing applications, issuing licensing, and conducting inspections for the new product or technology. If the manufacturer resides in multiple jurisdictions, it may be a collaborative effort between Agreement States. The regulatory products resulting could consist of a Sealed Source and Device Registry Sheet, if appropriate, a set of licensing guidance which all programs (Agreement States and NRC) could use in the review of applications for the use of the new device or product, and revised inspection guidance.

3. If a new use of material or new modality is not identified as a result of the survey at the OAS annual meeting, the OAS Executive Board will notify NRC that Agreement States failed to identify any candidate new use of material or new modality. OAS and NRC could decide at that point to: (a) defer the pilot project and resurvey the Agreement States at the next available opportunity (CRCPD meeting in May 2003) (b) eliminate option #4, new use of material or new modality regulatory products as a pilot project (c) if option #4 is eliminated, OAS and NRC jointly decide a replacement project.

Group Organization and Operations

OAS Executive Board:

Bill Sinclair, Chair, Utah
Pearce O' Kelley, Chair Elect, South Carolina
Kathy Allen, Past Chair, Illinois
Stan Fitch, Secretary, New Mexico
Ken Weaver, Secretary Elect, Colorado

Agreement State Personnel:

To be determined

Logistics and travel support for this pilot project, including travel and per diem expenses will be provided by the NRC.

Report Timeframe

If a modality or new use is identified at the 2002 OAS annual meeting, the lead Agreement State, groups of Agreement States, or individual experts within the Agreement States will complete the necessary regulatory products (which may include sealed source and device registry sheet, inspection and/or licensing guidance) and provide them to the Agreement States and the NRC for comment within nine months of the annual meeting (around July 15, 2003). Comments then will be considered and regulatory products finalized prior to the 2003 OAS annual meeting.

If no modality or new use is identified at the OAS at the 2002 annual meeting, the OAS Executive Board and the Director, OSTP will set aside time following the November monthly teleconference to discuss next steps (whether to continue to solicit candidate new uses or modalities or to abandon the project and identify a new project)

CHARTER
Writing Team to Revise IMC 2800, Materials Inspection Program
February 28, 2002

Background

On November 14, 2000, the Mallinckrodt Lessons Learned Task Group Report (Phase I) recommended specific actions to NMSS as short-term changes, long-term changes, rulemaking, referral to Phase II (review of the entire materials program), and referral to the National Materials Program Working Group. The Phase I recommendations addressed IMC 2800 and IP 87110-series that describe the materials inspection program. NMSS developed an action plan that was provided to the Phase II Review Group.

On August 13, 2001, the Phase II Byproduct Materials Review Report endorsed the majority of the recommendations that had been referred by Phase I, thereby encouraging NMSS to complete action on those items. Phase II recommended broad changes to NMSS policies, procedures, and processes to improve effectiveness and gain efficiencies to save NMSS resources for the materials program. Phase II recommendations addressed IMC 2800 changes and provided resource estimate costs and savings for implementation of each recommendation.

With input from the Regional Administrators, NMSS considered this information and committed to implement the Phase II recommendations, including the endorsed Phase I recommendations. NMSS decided not to consider any impacts from potential additional security measures resulting from the September 11 terrorist activities at this time. NMSS will consider impacts from security considerations based on information available from the Commission

Objectives

In order to implement Phase I and Phase II recommendations and conserve resources for the materials program in the remainder of FY02 and thereafter, the Writing Team (WT) is chartered to revise IMC 2800 and its associated non-medical Inspection Procedures (IP) and non-medical Temporary Instructions (TI) in order to align the materials inspection program with the risk-informed and performance-based regulatory approach

The WT will incorporate innovative approaches not included in Phase I and II recommendations for the implementation of the inspection process to achieve long-term increases in effectiveness and efficiency.

Scope of Work

The WT will revise IMC 2800, IP 87110-series, and TIs to implement the following Phase II recommendations that specifically addressed IMC 2800:

- II-5 (revise inspection priorities),
- II-9 (inspector empowerment),
- II-10 (streamlined inspection preparation),
- II-11 (initial inspections),
- II-12 (field office inspections), and
- II-16 (expanded use of NRC Form 591).

The WT will not validate the risk-informed inspection priorities determined by the Phase II Review Group. Implementation of II-6 (periodic assessment) will provide the opportunity to revisit this issue in the future.

The WT may select additional Phase I and II recommendations to be included in the revisions, e.g., II-6 (periodic assessment) and II-7 (performance-based IP's).

The WT will revise the seven non-medical IPs (87110, 87111, 87112, 87113, 87114, 87117, 87120) and will coordinate during this period with another writing team that will be revising the four medical IPs (87115, 87116, 87118, and 87119) for the implementation of revised Part 35.

The WT will initiate a Temporary Instruction for the revised Materials Inspection Program (TI 2800/033) in order to evaluate resource savings for the materials program. The WT will incorporate selected Phase I and II recommendations for IMC 2800 into TI 2800/033. The revisions to the IP 87110-series will not include the interim compensatory measures (ICM). A separate TI may be developed by other staff for the ICM. However, if information is available from staff actions regarding security that could influence the routine inspection program, this information will be considered in the final version of IMC 2800.

Organization and Operations

Under the expedited process, the roles of the WT and Pink/Red Team (PRT) are as follows. The PRT is responsible for providing policy direction to the WT and will be engaged regularly throughout the process. The WT provides the first draft of revised IMC 2800 to the PRT for review and comment before initiating TI 2800/033 on April 1, 2002. Interim approvals are not required on subsequent draft revisions of IMC 2800, TIs already in effect, or the IP 87110-series. At the end of the schedule, the WT will submit final versions of the revised products for the PRT's approval that will be substituted for the Office concurrence process. This organization and operation will accomplish the objectives set forth above within the expedited schedule indicated below. Following are the members of the WT and PRT.

Writing Team		Pink/Red Team NMSSThomas Young (Team Leader), Anita Turner, Jim Smith	
Region I	John McGrath	NMSS	Patricia Holahan
Region II	John Pelchat	Lawrence Kokajko	
Region III	Jamnes Cameron	Rll	Douglas Collins
Region IV	Michael Fuller	RIV	Dwight Chamberlain
OSTP	Richard Blanton	OSTP	Josie Piccone
O.S Rep	Robert Gallagher (Massachusetts)	OGC	Stuart Treby

Expedited Schedule

February 6, 2002	WT Teleconference, NMSS explains tasks and initial assignments to the appointed members
February 25 - 28, 2002	WT, 1 st draft (revised IMC 2800 and TI 2800/033) for PRT
February 28, 2002	PRT approves WT Charter
March 1, 2002	WT provides 1 st draft to PRT
March 5, 2002	PRT comments on 1 st draft due to WT
March 6 - 22, 2002	WT revises TI 2800/033
March 25 - 29, 2002	WT finalize TI 2800/033 and develop training and implementation plans for TI 2800/033 roll out
March 31, 2002	WT issues TI 2800/033
April 1 - 14, 2002	WT, Regional training and implementation for TI 2800/033

April 15, 2002 - March 31, 2003
July 2002
August 2002
October 1, 2002
November 2002
April - May 2003
July 1, 2003

Pilot use of the TI 2800/033 and collection of data
WT 1st draft of IP 87110-series
WT provides 1st draft of the revised IP 87110-series to PRT
Implementation of IP 87110-series.
Mid-pilot evaluation of data (April - September, 2002)
Final analysis of data and develop final versions for PRT
Final versions effective

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