

June 18, 2004

MEMORANDUM TO: The Management Review Board

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FROM: Working Group To Evaluate the NRC's Two-Person Rule **/RA/**

SUBJECT: RE-EVALUATION OF 10 CFR 34.41(a) COMMONLY KNOWN AS
THE TWO-PERSON RULE

PURPOSE:

To complete the action recommended by the Integrated Materials Performance Evaluation Program (IMPEP) Report on the Texas Agreement State Program August 27-31, 2001, Final Report (IMPEP Report) (Attachment 1 contains an excerpt from the IMPEP Report) that the Nuclear Regulatory Commission "(NRC), in coordination with the Agreement States, reevaluate the two-person rule to assess the effectiveness of the intended outcomes, including experience from past events, and propose a strategy and rule interpretation that best achieves the goal of safety." (IMPEP Report at Section 4.1.2)

BACKGROUND:

NRC's two-person rule, effective on June 27, 1998, requires that, "[T]he additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry." When the two-person rule was developed, there was strong and sustained support from the states, licensees, and industry for the concept of having at least two qualified individuals present whenever radiography is performed at temporary job sites. The expectation of the two-person rule, as expressed in the Statements of Considerations (SOC), is that, at a temporary job site, the second qualified individual would be able to secure the restricted area and the source and provide aid, as needed. In the SOC, the Commission stressed that having a second qualified individual is particularly important when radiography is performed where a radiographer alone may not be able to control access to the restricted area. Additionally, the second person should be trained in order to provide a safe working environment for radiography personnel, workers, and other members of the public at a temporary job site.

The draft IMPEP Report concluded that the Texas Department of Health's (Department) implementation of its two-person rule in Title 25, Section 289.255(v)(7)(G) is not compatible with the NRC's two-person rule in 10 CFR 34.41(a) which is designated as a Category B for

compatibility purposes. (Category B requires the elements of a state's regulation to be essentially identical to the elements of the NRC's regulation due to trans-boundary impacts.)

The IMPEP review team requested that the NRC Office of the General Counsel (OGC) also review the Department's rule. OGC found that while the Department's rule requires licensees to provide, at a minimum, two radiographic personnel for each exposure device in use for any industrial radiography conducted at a location other than at a permanent radiographic installation, it does not require the second qualified individual to observe radiographic operations. Because the Department's rule allowed for a "different interpretation," OGC concluded that the Department's rule was not compatible.

The Department responded to the draft IMPEP Report (Attachment 2). While it agreed that at least two qualified individuals should be required at a temporary job site, it disagreed with NRC's prescriptive implementation of the surveillance requirement for a two-person crew. The Department asserted that its implementation of a two-person rule in 1986, along with specific training requirements, more directly address the historical root causes of the large number of industrial radiography over-exposures seen prior to adoption of the Department's regulation.

The Management Review Board (MRB) believed that the Department presented sufficient information to warrant reconsideration of how the rule could be implemented. Therefore, in June 2002, The Office of Nuclear Materials Safety and Safeguards (NMSS) coordinated with the Office of State and Tribal Programs (STP), the Conference of Radiation Control Program Directors, Inc. (CRCPD), and the Organization of Agreement States (OAS) to establish a Working Group (WG) to re-evaluate the NRC's implementation of the rule. Attachment 3 provides the Working Group's Charter and the list of WG members, which included staff from NMSS, STP, Office of Enforcement (OE), OGC, Region IV/Division of Nuclear Material Safety (DNMS), and a representative from OAS and CRCPD.

WG OBSERVATIONS:

The WG made the following observations, discussed in Attachment 4, during its review:

- Since its effective date, the NRC has consistently implemented the two-person rule to require both qualified individuals to maintain continuous direct visual surveillance when radiographic operations are being conducted.
- The WG interviewed nine Agreement States about the implementation of their two-person rule. Six of nine Agreement States allow licensees the flexibility to determine if radiographic operations can be conducted safely when the first radiographer is able to observe operations and prevent intrusion into the restricted area while the second radiographer is involved in a related activity nearby. The three remaining states indicated that they required both radiographers to provide direct visual surveillance during radiographic operations.
- The WG was not able to attribute events involving industrial radiography to the failure of the two-person rule, much less to isolate the surveillance component of the regulation, because the effectiveness of the two-person rule has not been isolated from the other components in the regulatory framework.

- The WG found that risk information obtained from NUREG/CR-6642 does not support the manner in which NRC requires the two-person rule to be implemented as a requirement to enhance safety. The WG found that during routine operations, the requirement to have an additional qualified individual present may actually increase overall worker occupational radiation exposure, thereby increasing the overall societal latent cancer risk from routine operations.
- The WG found that using only two persons to provide surveillance of radiography operations may not always be adequate to prevent unauthorized access to restricted areas by members of the public. However, to be present and to be exposed to the radiation field in instances when radiographic operations are performed at temporary job sites merely to meet the requirements of the two-person rule, would not be considered As Low as is Reasonably Achievable (ALARA).
- When the two-person rule was enacted under the previous compatibility designations, the SOC indicated Agreement State compatibility for operational safety standards, i.e., Subpart D- Radiation Safety Requirements, which includes §34.41, as Division 2 matters of Compatibility. In 1997, the Joint Working Group on Adequacy and Compatibility transposed those compatibility determinations to the current designations. While reviewing the compatibility designations, the WG noted a difference in the designations between §34.41 and §34.51 for the same essential objective, surveillance. In §34.41 the surveillance component is designated compatibility Category B while in §34.51, it is designated Category C.

OPTIONS:

Option 1. No Rulemaking; No Additional Guidance (Status quo)

The two-person rule would remain as compatibility Category B. No effort would be taken to modify the rule or guidance in terms of today's risk-informed, performance-based regulatory environment. Additionally, no additional information would be issued to states or licensees to clarify the policy on which the rule was based, or further explain NRC's expectations as to how the rule should be implemented in order to meet the current compatibility category designation. Those Agreement States not in conformance with the present rule would be required to revise their regulations in order to ensure that they are essentially identical to those of NRC's rule in order to be rated as "satisfactory" in the IMPEP Non-Common Performance Indicator I - Compatibility Requirements.

This option would conserve NRC rulemaking and guidance development resources; however, it would not clarify the NRC's expectation regarding the surveillance component of the regulation during radiographic operations at a temporary job site (evidenced by the fact that at least six Agreement States are currently implementing this component differently). Additional Agreement State program incompatibility issues may develop and remain unresolved for lack of incentives linked to actual safety and could be confusing for licensees who operate in multiple jurisdictions. In addition, the option disregards 10+ years of information/data demonstrating that another implementation of the surveillance component of the rule is also viable and

achieves the safety goals of the regulation. Finally, if this option were selected, NRC may miss an opportunity to reduce unnecessary regulatory burden.

Option 2. No Rulemaking; Provide Risk-Informed, Performance-Based Implementation Guidance for the Surveillance Component of the Rule

This option does not require rulemaking. 10 CFR 34.41(a) would remain unchanged and a compatibility Category B.

NRC would issue guidance in a Regulatory Information Summary (RIS), modifying the NRC's current interpretation of the two-person rule. The RIS would indicate that the second qualified individual must remain at the temporary job site and must be cognizant of the site-specific circumstances when radiographic operations are in progress. However, licensees would have the flexibility to allow the qualified individual to engage in other related activities such as developing film in a nearby darkroom, rather than being required to maintain constant visual surveillance when the radiographer, alone, can observe the restricted area and prevent unauthorized entry into it.

Under this option, NRC and the Agreement States would align inspection and licensing guidance with the RIS. These documents would emphasize the performance-based objective for requiring a second qualified individual when radiographic operations are conducted at temporary job sites. The objectives are to: (1) observe operations; (2) be capable of preventing unauthorized entry into the restricted area; and (3) provide assistance, when necessary. The revision would preserve these objectives while factoring in site specific circumstances that should be considered when determining if a single radiographer can safely observe the restricted area and prevent unauthorized entry into the restricted area while the other qualified individual is performing some other job-related task. Training should stress that the second qualified individual must remain at the temporary job site during radiographic operations and be observant, adjusting his/her activities to site specific circumstances, when radiographic operations are in progress. In addition, the RIS would discuss the NRC's expectations of what would be acceptable in determining whether the second qualified individual is able to provide "immediate assistance" and is "nearby."

Under this option, the NRC and the Agreement States alignment and implementation of the revised guidance should provide greater uniformity in nation-wide implementation and more licensee flexibility in conducting operations at certain job sites over the current *status quo*.

Option 3. No Rulemaking; Change the Surveillance Component in 10 CFR 34.41(a) from Compatibility Category B to Category C

This option does not require rulemaking. This option would revise the surveillance component for the second qualified individual in §34.41(a). Although not a proposed rule, staff would use a

process similar to the one outlined in SA-200¹ and MD 5.9 to change this requirement to a compatibility Category C. The requirement to have two qualified individuals at a temporary job site would remain compatibility Category B.

The WG's review of the two-person rule disclosed an issue regarding the surveillance component in §34.41(a). The compatibility designation of B for this section is inconsistent with the compatibility designation for the requirement in §34.51, Surveillance, which is designated a Category C. In its review of the rule's background, the WG could not identify a compelling rationale that accounts for the difference in the compatibility categories. Changing the compatibility Category to C for the surveillance component in §34.41(a) would address the compatibility issue raised by the IMPEP Report, taking into account NRC's current risk-informed, performance-based regulatory environment.

In addition to changing the compatibility designation, this option would also require the alignment of inspection and licensing guidance in a manner similar to that described in Option 2. Agreement States would not have to change their regulations under this option, however, certain states may need to revise their policy and guidance in order to ensure the appropriate level of uniformity within the national materials program.

The trans-boundary implications of the requirement would not be impacted by changing the surveillance component of that requirement from compatibility Category B to Category C. Implementation of the surveillance component as a Category C would permit flexibility for the states to be more restrictive than NRC while implementing the essential objectives of the rule, as clarified in Option 2, and is consistent with NRC's position on risk-informed, performance based regulation. Additionally, Agreement State potential program incompatibility issues would be resolved or avoided, and NRC would be able to reduce unnecessary regulatory burden based on the specific information that is collected and analyzed to support this action.

While the WG viewed this as a viable option, it would require more resources than Option 2, e.g., (1) the development of a *Federal Register* Notice summarizing the WG's concern regarding the current designation of the surveillance component in order to compile information from the Agreement States and licensees regarding their experiences with the effectiveness and efficiency of the NRC's current implementation of the surveillance component of the rule; (2) the development of a Regulatory Information Summary (RIS); and (3) the revision of current inspection and guidance documents.

Option 4. Rulemaking; Provide Risk-Informed, Performance-Based Implementation Guidance for the Surveillance Component of the Rule; Consider Changing the Surveillance Component in 10 CFR 34.41(a) from Compatibility Category B to Category C

Under this option, NRC would pursue rulemaking to revise § 34.41(a) to reflect the regulators' expectations of the second qualified individual's activities when radiographic operations are being conducted at temporary job sites. The two-person crew requirement at temporary job

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The in-process revision of SA-200 has been designated for use.

sites would not be changed under this option. The revision process would take into account NRC's current risk-informed, performance-based regulatory framework. Additionally, the administrative process would involve the early and substantive involvement of the Agreement States in the process as well as the involvement of members of industry and the public who wish to provide comments. However, the unintended consequence of this option might be that the two-person crew requirement would also be changed. Regardless of the outcome, the Agreement States would be required to make conforming changes to their regulations to maintain adequacy in the area of Legislation and Program Elements Required for Compatibility.

Similar to Option 2, this option would also include risk-informed, performance-based implementation guidance for the surveillance component of the revised rule. This would require the Agreement States to change their licensing and inspection guidance. In addition, similar to Option 3, this option would require a reconsideration and re-designation of the compatibility category designation.

RECOMMENDATION:

The consensus of the WG with a differing view (Attachment 6) is to support Option 2 because it provides a risk-informed, performance-based implementation of the surveillance component in §34.41(a) while retaining the benefit of a two-person crew at temporary job sites.

The RIS would address the risk-informed, performance-based surveillance component in §34.41(a), focusing on the function of the second radiographer or other qualified individual in circumstances where (1) the radiographer alone is able to control access to the area, e.g., when the circumstances at the site allow an unobstructed view of the restricted area, other individuals are not present at the site, and the radiographer alone can control the area and prevent unauthorized entry during radiographic operations; and (2) the second radiographer or additional qualified individual is needed to maintain safety during radiographic operations, e.g., when circumstances at the site make it difficult or impossible for the radiographer to control access to the area, and is expected to maintain an awareness of the ongoing radiographic operations. Training should stress that the rule requires the second qualified individual to be cognizant of the ongoing radiographic operations and to be able to reinforce the appropriate radiation safety responses, when necessary.

The consensus of the WG is that this option recognizes that the goal of safety is accomplished in the Agreement States that have alternative requirements and approaches to implementation, which are adequate to protect health and safety at temporary sites where two-person crews are required for industrial radiography. This option appears to be an efficient mechanism for accomplishing the need to allow the rule to achieve consistent implementation nationwide. It conserves NRC rulemaking resources, although it would require minimal expenditure of resources to provide the appropriate guidance to affected licensees.

Although the WG was not asked to consider implementation cost, it appears that this option has the potential to be the least expensive way for all parties to achieve greater compatibility and consistency in the surveillance component in §34.41(a).

The requirement that "Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 10 CFR 34.43(c)...Radiography may not be performed if only one qualified individual is present," would be retained.

Finally, the Agreement States have long wanted direct access to the Technical Assistance Requests (TARs) involving radiation control programs in order to assist them on licensing issues. The WG also suggests that Technical Assistance Requests (TARs) be made available on the NRC's webpage so that all radiation control programs can quickly access and use any new guidance these TARs provide.

Attachments:

1. IMPEP Report on Texas Agreement State Program
2. Texas IMPEP Response
3. Charter and list of WG members
4. WG Observations
5. Regulatory Framework
6. Differing View