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WINSTON & STRAWN LLP

Electronic
Letterhead

1400 L STREET, N.W., WASHINGTON DC 20005-3502
202-371-5700

35 W. Wacker Drive
Chicago IL 60601-9703
312-566-8600

200 Park Avenue
New York, NY 10166-4193
212-894-6700

38th Floor, 333 South Grand Ave
Los Angeles, CA 90071-1843
213-615-1700

101 California Street
San Francisco CA 94111-6804
415-891-1000

43 Rue de Rome
1204 Geneva, Switzerland
41-22-317-75-75

21 Avenue Victor Hugo
75116 Paris, France
33-1-83-64-82-82

City Point, 1 Ropemaker Street
London, England EC2Y 9HT
44-207-183-1025

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Annette Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attn: Rulemakings and Adjudications Staff

**Re: Comments on Proposed Rule Permitting Risk-Informed
Categorization and Treatment of Structures, Systems
and Components for Nuclear Power Reactors
(68 Fed. Reg. 26,511 (May 16, 2003)) (RIN 3150-G42)**

Dear Ms. Vietti-Cook:

Please find herein comments submitted by Winston & Strawn, on behalf of the Licensing and Design Basis Clearinghouse ("LDB Clearinghouse"),¹ concerning the subject proposed rule. Below we provide general comments, comments in regard to specific questions posed by the Commission, and comments on specific aspects of the proposed rule or its accompanying information.

The LDB Clearinghouse supports the issuance of the rule and believes that it provides benefits for both the Nuclear Regulatory Commission ("NRC") Staff (the "Staff") and licensees in determining how and where to best focus resources in a manner that protects the public health and safety. In summary, our comments reflect and emphasize the following observations and conclusions:

- The risk-informed voluntary option set forth in the proposed rulemaking, will adequately protect the public health and safety, consistent with the Commission's statutory authority.

¹ The LDB Clearinghouse is a consortium of nuclear utilities that follows NRC activities related to licensing and design basis issues.

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- The Commission may rely on high-level objectives, rather than prescriptive criteria, in specifying the requirements governing (1) the adequacy of a licensee's probabilistic risk assessment, and (2) the alternative treatment for safety-related, low risk-significant structures, systems, and components.
- The NRC Staff should consider conforming revisions to the NRC's inspection and enforcement policy and guidance.
- The proposed feedback process for incorporating information from operating experience, both plant-specific and industry-wide, should reduce the uncertainty in the categorization process.

I. General Comments

The proposed rule would provide licensees with an option to categorize structures, systems, or components ("SSCs") into classes based on their risk significance and whether or not they are safety-related. For those safety-related, low-risk-significant SSCs, licensees who elect to implement the proposed rule could reduce or eliminate certain special treatment requirements (as listed in the proposed rule), while continuing to ensure that these SSCs are capable of performing their design basis functions. The proposed rule is one of the NRC Staff's initiatives to risk-inform agency regulations, consistent with the Nuclear Regulatory Commission ("NRC" or "Commission") policy on the use of risk assessment methods² and its Fiscal Year 2000 – 2005 Strategic Plan performance goal to reduce unnecessary regulatory burden on stakeholders through the application of, *inter alia*, risk-informed initiatives.

The LDB Clearinghouse has reviewed the statutory and legal basis for the proposed rule and believes that it is consistent with the Commission's authority under the Atomic Energy Act of 1954, as amended ("AEA" or "Act") for the following reasons:

- In accordance with Sections 161i.(3) and p. of the Act, the Commission has the discretion to implement any regulatory scheme that it has determined will provide adequate protection of public health and safety.³
- The Commission explains in the supplementary information accompanying the proposed rule that it has determined the rule will provide reasonable assurance of

² See n. 4 *infra*.

³ 42 U.S.C. §§ 2201(i)(3), (p).

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adequate protection of public health and safety, as the Staff developed the proposed rule by applying the principles of the Commission's policy on the use of probabilistic risk assessment ("PRA") methods in NRC activities. These principles, which have since been incorporated into NRC regulatory guidance on using risk-informed insights for decision-making,⁴ provide that:

- The net increase in plant risk is small;
 - Defense-in-depth is maintained;
 - Safety margins are maintained; and
 - Monitoring and performance assessment strategies are used.
- The proposed rule is consistent with the Commission's policy to increase the use of PRA in regulatory matters, and to use PRA and associated analyses (*e.g.*, sensitivity studies, uncertainty analyses, and importance measures) to reduce unnecessary conservatism associated with current regulatory requirements.⁵
 - The NRC has previously approved an exemption from special treatment requirements for the South Texas Project, Units 1 and 2 ("STP") as a proof-of-concept for the implementation of the proposed rule, and has applied lessons learned from the STP review in developing the proposed rule.⁶
 - Several other plants (Wolf Creek, Surry, Quad Cities, and Palo Verde) have conducted pilot activities, with NRC Staff participation, of certain elements of the proposed industry implementing guidance to identify potential improvements to the guidance.⁷

⁴ 68 Fed. Reg. at 26,529, citing "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," 60 Fed. Reg. 42,622 (Aug. 16, 1995), and Regulatory Guide 1.174 (Rev. 1), "An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis" (Nov. 2002).

⁵ 60 Fed. Reg. at 42,628.

⁶ 68 Fed. Reg. at 26,532.

⁷ *Id.*

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- Nothing in the Act, in NRC policy, in current regulations, or in the proposed rule would preclude Commission adoption of a risk-informed regulatory approach. The Commission also may adopt alternative approaches to achieve its statutory mandate for ensuring adequate protection of public health and safety.⁸

On the basis of these considerations, the LDB Clearinghouse believes that the proposed rule is within the Commission's statutory authority and discretion, and that the proposed rule will provide the requisite level of assurance of adequate protection of public health and safety.

II. Comments on Specific Questions for Public Input

In Section VI.2.0 of the supplementary information accompanying the proposed rule, the Commission set forth four questions for public input.⁹ The LDB Clearinghouse comments on each of these four questions follow.

VI.2.1 PRA Requirements

An important element in the categorization process for SSCs is the information obtained from a plant-specific PRA. The PRA results and insights provide a significant portion of the underlying basis for determining the risk significance of SSCs for categorization. Accordingly, the proposed rule establishes high-level objectives for ensuring the adequacy of the plant-specific PRA that would be used to implement the proposed rule. In addition, the NRC has issued proposed guidance for determining the technical adequacy of PRA results for risk-informed activities.¹⁰

The proposed rule requires that, as a minimum, the plant-specific PRA must include internal events, at power, and must have been subjected to a peer review process. In Section VI.2.1, the Commission indicates that an adequate PRA must be capable of determining both core damage frequency ("CDF") and large early release frequency ("LERF") and provide

⁸ See AEA Sections 161i.(3), p.

⁹ 68 Fed. Reg. at 26,545-47.

¹⁰ Draft Regulatory Guide DG-1122, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities" (Nov. 2002).

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Level 2-type results.¹¹ In addition, the proposed rule would allow licensees to use non-PRA methods to address other modes and hazards in the categorization process. Importantly, the proposed rule would require a licensee to submit information about its PRA and these other methods, including information about the quality and level of detail regarding all of the methods to be used.

The Commission seeks input as to whether it should require a Level 2 internal and external initiating events, all-mode, peer-reviewed PRA that must be submitted to, and reviewed by, the NRC. The LDB Clearinghouse believes that the current proposed requirements for PRA scope and quality provide an adequate level of assurance for protection of public health and safety, consistent with the Commission's statutory mandate in the Act, for the following reasons:

- The proposed PRA requirements are consistent with the Commission's policy for the use of PRA in regulatory decisions, which provides that PRA and associated analyses should be used in regulatory matters, where practical within the bounds of the state-of-the-art PRA.¹²
- A licensee must implement the provisions of the proposed rule through an amendment to its operating license. As part of the NRC Staff review of the license amendment application, the Staff will review and approve the licensee's proposed PRA, the basis for sensitivity studies and evaluations (including non-PRA analyses), and results of the PRA review process (*i.e.*, peer review against established standards and NRC-approved acceptance criteria).
- Peer review of a PRA against specific criteria contained in industry-drafted standards, which will be approved by the NRC prior to use by licensees, should provide an adequate level of assurance that the PRA is of sufficient quality and scope. Accordingly, there is no need for excessive detail in the rule, which as drafted will allow the appropriate level of flexibility for licensees to improve their PRA methodology through technological advancements.
- The proposed rule would require that a licensee's Integrated Decision-Making Panel ("IDP") include individuals with PRA expertise. The IDP supplements the

¹¹ A "Level 1" PRA refers to an internal events PRA which analyzes core damage release frequency. A "Level 2" PRA refers to an expanded PRA which analyzes radionuclide release frequency from severe accidents.

¹² 60 Fed. Reg. at 42,628.

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PRA results, especially for assessing initiating events and plant operating modes, or SSCs, not modeled in the PRA. In addition, the IDP may categorize SSCs as risk-significant, in spite of PRA results to the contrary.

- The proposed rule includes provisions for addressing initiating events (internal and external), SSCs, and plant operating modes not specifically modeled in the plant-specific PRA.
- The proposed rule would require periodic evaluation of the implementation of the approach and identify necessary adjustments, including to the PRA.
- NRC-approved standards will provide a sufficient basis for identifying elements of an adequate PRA. If, at any time, the NRC determines that these standards are inadequate, it has the authority to issue orders, or take other action, to ensure adequate protection of the public health and safety.

Together, these provisions will ensure adequate protection of the public health and safety, as mandated in the AEA.

VI.2.2 Review and Approval of Treatment for RISC-3 SSCs

The Commission posed a second question for comment concerning NRC review and approval of a licensee's proposed treatment program for RISC-3¹³ SSCs. As now proposed, the rule envisions only NRC review and approval of the licensee's SSC categorization process. The rule sets forth high-level treatment requirements, but does not require NRC review and approval of the specific processes a licensee would use to meet those requirements. The Commission has asked whether it should instead adopt a regulatory requirement that the NRC review and approve a licensee's proposed RISC-3 SSC treatment program.¹⁴

The premise of the proposed rule is that the categorization of SSCs will be robust and provide high confidence that the safety significance of SSCs is correctly determined by

¹³ The four categories of risk-informed safety class ("RISC") SSCs are: RISC-1 (safety-related SSCs that perform safety-significant functions); RISC-2 (nonsafety-related SSCs that perform safety-significant functions); RISC-3 (safety-related SSCs that perform low safety-significant functions); and RISC-4 (nonsafety-related SSCs that perform low safety-significant functions).

¹⁴ 68 Fed. Reg. at 26,546.

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considering all relevant information.¹⁵ The categorization process has been structured to ensure that all relevant information is considered in a manner that ensures the Commission's criteria for risk-informed applications are satisfied (*i.e.*, maintaining defense-in-depth, maintaining safety margins, ensuring that any risk change is small, and monitoring performance). The categorization process must include an adequate plant-specific PRA, supported by other analyses; the use of an IDP; and a periodic evaluation of the effects of treatment changes.

Under this robust categorization process, special treatment requirements for SSCs may be removed for components categorized as RISC-3. The proposed rule specifics high-level objectives for four processes that must be controlled through the RISC-3 alternative treatment:

- Design control;
- Procurement;
- Maintenance, inspection, testing, and surveillance; and
- Corrective action.

The LDB Clearinghouse believes that NRC review and approval of the specific RISC-3 treatment is not necessary. Specifying high-level objectives for these four processes is within the NRC's broad statutory authority, and will provide adequate assurance for the protection of public health and safety for the following reasons:

- The proposed rule requires that any RISC-3 treatment continue to ensure that those SSCs (and their replacements) remain capable of performing design basis functions.
- The proposed high-level treatment requirements for monitoring and corrective action will ensure that a licensee monitors RISC-3 SSCs and that any important deficiencies are corrected.
- Under this robust categorization process, any deficiencies with RISC-3 treatment are likely to be of low risk-significance.

¹⁵ 68 Fed. Reg. at 26,514.

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- Licensees may apply varying levels and types of treatment to SSCs, depending on such factors as the type of equipment, design basis function (*e.g.*, active versus passive), or preventative maintenance of equipment.
- The industry has initiated efforts to develop generic guidance on acceptable RISC-3 treatment alternatives, which licensees will likely use to develop plant-specific treatment programs.
- The NRC finds it acceptable to allow some increased likelihood of failure of RISC-3 SSCs because such an increase can be tolerated without significantly impacting safety.¹⁶
- The NRC has already concluded that effective implementation of the treatment requirements provides reasonable confidence, consistent with the Commission's statutory mandate, in the capability of RISC-3 SSCs to perform their safety functions under normal and design basis conditions, consistent with the low safety significance of the RISC-3 categorization.¹⁷

The LDB Clearinghouse believes that these high-level objectives, combined with the requirements to maintain the capability to perform the design basis functions and the robust categorization process, will ensure adequate protection of public health and safety.

VI.2.3 Inspection and Enforcement

The third issue on which the Commission sought comment concerns the need for new or revised inspection or enforcement guidance from the Commission following or concurrent with final rule promulgation.¹⁸ The proposed rule contains no provisions that specifically address inspection and enforcement. The NRC Staff has noted, however, that with respect to improving efficiency and effectiveness in its regulatory processes, the risk-informed rulemaking "would aid in bringing the regulation in closer agreement with the risk-informed

¹⁶ 68 Fed. Reg. at 26,518.

¹⁷ 68 Fed. Reg. at 26,517.

¹⁸ 68 Fed. Reg. at 26,546-47.

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approaches to inspection and enforcement.”¹⁹ The LDB Clearinghouse has considered this issue and submits the following comments for consideration:

- Section 161.c of the AEA authorizes the Commission to conduct studies and investigation as it may deem necessary or proper in enforcing the Act or regulations or orders thereunder.²⁰ The current NRC Enforcement Policy and Enforcement Manual provide high-level objectives for the NRC’s oversight of nuclear power reactors which are adequate to broadly address the provisions of the proposed rule without modification.
- NRC Inspection Manual Chapter 0305, “Operating Reactor Assessment Program,” provides guidance for implementing the risk-informed reactor oversight process (“ROP”) for assessing the overall safety of operating reactors. The Staff should consider revising this inspection guidance to acknowledge the potential for a licensee to voluntarily implement the provisions of 10 C.F.R. § 50.69.
- NRC Inspection Manual Chapter 0609, “Significance Determination Process,” provides guidance for determining the safety significance of inspection findings. The categorizing of SSCs into classes of risk and safety significance should be generally consistent with the approach in the equipment-related appendices and attachments for this manual chapter, which provide further guidance on assessing the significance of particular inspection findings. The Staff should consider revising this guidance to address potential overlap of the proposed rule with the significance determination process, and how such overlap should be dispositioned if inconsistencies result.
- The NRC Staff should consider permitting an interim period of enforcement discretion for the initial implementation of the proposed rule, to allow a licensee sufficient time to develop applicable procedures and programs. Under this approach, a licensee would have an opportunity to make initial adjustments in its categorization process, including to the PRA, without fear of an enforcement action for incomplete or inaccurate information during the transition period. This

¹⁹ SECY-02-0176, “Proposed Rulemaking to Add New Section 10 CFR 50.69, ‘Risk-Informed Categorization and Treatment of Structures, Systems, and Components’” (Sept. 30, 2002), at 3.

²⁰ 42 U.S.C. § 2201(c).

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action would be consistent with the manner in which the reactor oversight issues were handled during initial rule implementation.

- Inspection of a licensee's implementation of the proposed rule should focus on the categorization process, including the PRA, periodic evaluations of the process, and corrective action for identified deficiencies, rather than on specific equipment issues regarding the elimination of special treatment of RISC-3 SSCs. By definition, any deficiencies of RISC-3 SSCs would be of low safety significance, and should thus be of reduced enforcement focus.
- The NRC Staff should ensure that the integration of the risk-informed ROP, the requirements to assess the risk impact of removal of equipment prior to performing maintenance, and the risk-informing of special treatment requirements is coherent. NRC inspectors should be trained in the risk-informed aspects and integration of these related regulatory processes.
- As a result of implementing the proposed rule, a licensee may be required to enhance the treatment of RISC-1 and RISC-2 SSCs to ensure their capability and reliability to function in support of key assumptions of the categorization process. The NRC Staff should consider using a focused inspection team for the first two cycles of inspection to ensure consistency in the NRC's oversight of this element (as well as others) of a licensee's implementation of the newly-permitted approach.

The LDB Clearinghouse believes that these revisions to the inspection and enforcement policy and guidance will provide the appropriate level of NRC oversight of the implementation of the voluntary option in the proposed rule.

VI.2.4 Operating Experience

The final topic presented by the Commission for comment involves the role that plant and industry operating experience could play in reducing the uncertainty associated with the effects of treatment on performance, and specifically the uncertainty associated with the potential effects of changes in RISC-3 treatment on the reliability and common-cause failure potential of the RISC-3 SSCs.²¹ Sources of uncertainties include uncertainties in PRA models (*i.e.*, human error probabilities, common-cause failure probabilities, and items identified during

²¹ 68 Fed. Reg. at 26,547.

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the assessment of PRA adequacy²²) and uncertainties in failure rates of components.²³ The three elements of the proposed rule aimed at minimizing such uncertainty are:

- the requirement for evaluations (sensitivity studies) of the implementation of the approach (which will provide reasonable confidence that any changes in risk are small);
- the requirement to periodically review performance information to determine whether there are any adverse changes such that RISC-3 SSC unreliability values approach unacceptable values; and
- the requirement to make necessary adjustments to the categorization and treatment processes, including updating the PRA, based on periodic review of (1) changes to the plant, (2) operational practices, and (3) applicable industry operational experience.²⁴

The LDB Clearinghouse believes that the proposed rule contains adequate controls to maintain the Commission's statutory mandate to ensure adequate protection of public health and safety, for the following reasons:

- The proposed rule requires that the special treatment requirements continue to apply to the high-risk-significant SSCs. Thus, for these SSCs, there are no changes in treatment that would affect the reliability or capability of the SSCs to perform design basis functions. Further, the proposed rule would require a licensee to ensure that treatment for RISC-1 and RISC-2 SSCs supports key assumptions of the categorization process.
- In addition to the proposed requirement to maintain defense-in-depth, uncertainties are minimized by incorporating elements that are intended to add conservatisms back into the process (e.g., IDP, alternate treatment, periodic

²² Draft Regulatory Guide DG-1121, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance" (May 2003), at 5.

²³ *Id.* at 9.

²⁴ 68 Fed. Reg. at 26,550.

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reviews of the implementation of the process, limitations on selective implementation).

- Adjustments in the process, based on operating experience following the implementation of the program, will allow for improvements if deficiencies are identified.
- The high-level requirements for RISC-3 treatment are sufficient to address concerns that reductions in special treatment for RISC-3 SSCs might, collectively, be safety-significant, or result in common mode failures. Requiring controls (*i.e.*, alternate treatment), albeit at a reduced level, and factoring in operating experience, minimizes the potential for concurrent failures of RISC-3 SSCs, such that any increase in risk is small. Thus, consistent with the Commission's policy on the use of PRA, the proposed rule provides an adequate level of assurance of the protection of public health and safety.

With these considerations, the feedback process should ensure that licensees that elect to implement the voluntary option will make appropriate programmatic adjustments. In this manner, the adequate protection of public health and safety will be reassured on a continuing basis.

III. Comments on Specific Issues

A. Applicability to License Renewal

In the proposed rule, the NRC explains the applicability of the rule to the license renewal aging management requirements of 10 C.F.R. Part 54.²⁵ According to the NRC, the requirements in Part 54 are compatible with the approach in the proposed rule, including the use of risk information in establishing treatment (*i.e.*, aging management) requirements. We agree that the approach is compatible with license renewal requirements, as stated in the proposed rule applicability and scope statement.²⁶ We recommend that, to assist license renewal applicants in implementing this new regulatory option, the Staff issue guidance regarding the applicability of the proposed rule in the context of license renewal. The guidance should specifically discuss how the categorization process can be employed in risk-informing aging management programs.

²⁵ 68 Fed. Reg. at 26,527.

²⁶ Proposed 10 C.F.R. § 50.69(b)(1).

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B. Degraded and Non-Conforming Conditions and Equipment Operability Guidance

In order to ensure consistency of the overall NRC regulatory scheme with risk-informed initiatives, we urge the NRC to consider the potential for the risk-informed efforts generally, and the effort related to the categorization of SSCs specifically, to affect the processes for determining operability of components when degraded or non-conforming conditions are identified.²⁷ Accordingly, we recommend that, as a longer-term action, the NRC establish a mechanism for addressing the need for changes or clarifications in regulations or guidance in order to properly apply risk-informed insights in the operability processes that would be consistent with application of the risk-informed initiatives.²⁸

C. Discussion of Alternative Treatment Methods

In Section V.5.2 of the supplementary information accompanying the proposed rule, the NRC discusses alternate treatment methods. While we agree that some explanation of the proposed rule requirements is appropriate, the discussion is overly prescriptive and could be construed as inappropriately modifying or expanding on the actual regulatory requirements. For example, the discussion includes NRC "expectations" for developing and evaluating RISC-3 treatment that are more appropriately considered regulatory guidance for acceptable methods of implementing the requirements.

The proposed rule specifies the high-level treatment requirements for RISC-3 SSCs. If the NRC considers it necessary to prescribe acceptable methods for determining appropriate treatment methods, then the NRC should include this information in a regulatory guide. By including such prescriptive language in the supplementary information accompanying the proposed rule, it appears that the NRC is attempting to establish requirements for interpreting the proposed rule without including such requirements in the actual regulatory text. We recommend that the NRC retain the proposed rule language, and delete the prescriptive information from the supplementary information.

²⁷ NRC Generic Letter 91-18, "Information ... Regarding Two NRC Inspection Procedures On Resolution of Degraded and Nonconforming Conditions and On Operability" (Nov. 7, 1991), and Generic Letter 91-17, Revision 1, "Information to Licensees Regarding NRC Inspection Manual Section on Resolution of Degraded and Nonconforming Conditions" (Oct. 8, 1997).

²⁸ We understand that the NRC Staff has ongoing actions to review and revise its guidance concerning degraded and nonconforming conditions and equipment operability. We do not suggest that this activity be delayed to include risk-informed insights at this time.

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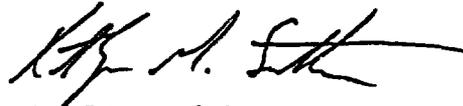
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IV. Conclusion

The LDB Clearinghouse generally supports issuance of the rule to provide a voluntary option to licensees who elect to implement a risk-informed approach for categorizing SSCs to reduce certain special treatment requirements. This is consistent with the Commission's goals and objectives and within the statutory mandates of the AEA to provide adequate protection of public health and safety. We request that the Commission consider our comments and recommendations in issuing the final rule.

If you have any questions concerning the comments, please contact us.

Sincerely,



Mark J. Wetterhahn
Kathryn M. Sutton
Counsel to the LDB Clearinghouse