November 19, 1996

Mr. Frank R. McCoy, III
Safety Management Implementation
Team Leader
Department of Energy
Room 7A-121
1000 Independence Avenue, SW
Washington, DC 20585

Dear Mr. McCoy:

On October 2, 1996, the DOE staff briefed the Board on the status of Recommendation 95-2 deliverables and provided draft material for our review, including Preliminary Draft-White Paper September 25, 1996, Reconciliation and Integration of Safety Directives and Initiatives, Implementation Plan for [DNFSB] Recommendation 95-2, Internal Management Action 1.b. The following staff and OGC comments pertain to that draft White Paper.

1. In general, the rate of change of the directive system, including changes proposed by this White Paper, is so great that it is likely to be difficult for DOE field elements to understand how to implement these changes. The draft White Paper appears to be at variance with DOE O 251.1-1 and supporting guidance, which the Board and staff have reviewed extensively.

   It is not clear whether this document is considered part of the directives system or whether the document is outside the system. Regardless, the White Paper proposes to establish a new way of doing business which is different from the recent new ways of doing business articulated in DOE O 251.1. Is this document a policy statement, an order, a manual, a guide, or something else?

2. Not only does this draft White Paper reflect a lack of familiarity with ongoing DOE directives efforts, such as DOE O 251.1, but defective provisions related to rules (regulations) and guidance reflect a distressing lack of understanding of the nature of requirements and the regulatory process.

   o The White Paper provides that "the contractor may submit a [sic] implementation plan that would grant the contractor a variance to comply with alternative standards in lieu of the specified regulatory requirements." Not only is this inconsistent with existing DOE regulations and Orders, this provision is contrary to existing legal precedent including U.S. Supreme Court holdings. Exemptions from DOE Orders must comply with the process in DOE O 251.1 (as detailed in M 251.1-1) or provisions in specific Orders, and exemptions from regulations must comply with the process required by 10 C.F.R. Part 820.

   o As mentioned, directives are defined to include regulations. However, directives are stated to be not mandatory for contractors unless included in a contract or
other legal instrument. This is incorrect. Directives which are also regulations are mandatory, regardless of incorporation in a contract or other legal document. If the contractors and their activities are the subjects of the regulation, the regulation is mandatory unless exempted.

- Directives are also defined to include guidance documents, manuals and technical standards. Directives incorporated in a contractor's SMS (safety management system) are declared to be requirements. Thus, guidance now becomes subject to enforcement as a requirement. We suggest that incorporation of guidance in the SMS constitute a commitment to implement the guidance, or an acceptable alternative, but would not elevate the guidance itself to a requirement.

- "Line management decides what directives and initiatives are contained in a contractor's SMS." This is acceptable if the decision is based on a rigorous and approved process, and the decision to include or reject a directive is subject to DOE management approval. Further, directives which are regulations would be applicable whether incorporated in the SMS or not, unless exempted under the appropriate regulatory process. (DOE management approval is not provided by the validation and endorsement body, which "reviews and endorses directives and initiatives," but does not participate in determining which apply to individual facilities and activities.)

3. Creating a Validation and Acceptance body adds another layer of administrative overhead to an already cumbersome process.

- A safety management program should be efficient and effective, staffed with qualified and capable personnel. As it is today, the Directives Management Board, chaired by Mr. Grumbly, is charged with resolving major directives system issues. In our experience, only Mr. Grumbly has had the determination, vision, and decision-making authority within DOE to make this system work. Adding yet another consensus body will lengthen, or at least complicate, an already tortured process and may undermine Mr. Grumbly's authority by placing another group in a position to second guess his decisions.

- What value does the V&A body add by endorsing technical standards? For example, the plutonium stabilization standard called for in Recommendation 94-1 was produced under the existing system by knowledgeable professionals. It is not clear how a V&A body would improve this process.

- Would the expertise of the contractors and labs be brought to bear as part of this V&A exercise? Would they, at least, make presentations of their own proposals? It is hard to judge how effective this process would be without some idea of how this important process/body would function.

- The work of this V&A body would appear to be daunting. Is there a permanent infrastructure anticipated; something like the staff of the NRC's advisory
committees?

4. *Unendorsed initiatives* appear to provide an alternate path for decision making which circumvents both the Directives Management Board and the V&A body. This is but another means to bypass the system without justification. (See comments on using implementation plans to secure *de facto* regulation and Order exemptions.) Admittedly, there will be exigent circumstances which will require fast action. Provisions could be made to fast track an initiative, with appropriate review and approval prior to implementation, or to implement an initiative in an emergency, but to ensure an immediate and appropriate review and approval.

5. The concept of *endorsed directives* would seem to require more thought.

   o Clearly the old Order system had its problems in that they were not uniformly applicable to all applications. Similarly, the new directive system will require tailoring to the hazard and the activity in the field. What then is to be understood by the concept of endorsement? The items which are of safety value to the field will have to be determined by specific application, and will generally not benefit from some high level endorsement from individuals who are not personally familiar with the work or are not technically qualified to judge its adequacy.

   o It is not clear how or why endorsed initiatives would or should become part of the Safety Management System Guide (G 450.4). Why should one site's exception or unique program become part of the standard approach, by assumption? How would this be done? By a series of appendices with alternate approaches?

   o An *initiative is* defined in the White Paper to be "an approved plan of action involving the collection, processing, or analysis of information resulting in options including program and resource impacts." This definition is not particularly enlightening, and seems inconsistent that an approved plan of action would *result in* options. Shouldn't the approved plan of action result in *selection* of an option for further action? The discussion would benefit from a few examples of initiatives.

6. HR is stated to manage directives other than rules or technical standards. Management includes direction and control over the use of the directives. This is an improper function for HR, which is not a technical organization. We suggest that HR administer the directives program rather than manage the directives.

7. The requirement to garner consensus as part of this process and to resolve all comments prior to moving forward is a prescription for gridlock. How are outliers to be handled? It would appear wiser to state that all comments will be "addressed," otherwise DOE may be establishing a higher standard than even NEPA would require.

   Sincerely,
Robert M. Andersen
General Counsel

c: Hon. Robert R. Nordhaus
   Mr. Mark B. Whitaker, Jr.
   Mr. Theodore A. Wyka, Jr.