FEB 23 1989

NOTE TO: Allen Whiting, CNWRA

FROM: Philip Altomare, NRC

SUBJECT: NRC RESPONSE TO 2/15/89 PA REORIENTATION QUESTIONS

The following comments were jointly provided by DHLWM and OGC in response to your 2/15/89 query.

1) TECHNICAL COMPONENTS OF PROOF AS A PROPOSED CONCEPT
In consideration of the proposed concept, NRC's CNWRA project management and legal staff are disturbed that your proposal would mix what is stated in the regulatory requirement with what is not stated in the regulatory requirement. As a consequence you will ascribe equal weights to the regulatory elements of proof (REOP) and the technical components of proof, as stated by your quote ""WHAT" must be demonstrated to prove compliance."

In developing the Program Architecture developmental process, if technical components of proof (TCOP) define ""WHAT" must be demonstrated to prove compliance," then the TCOP should be in the PURL as they will latter become REOP's. If TCOP's do not define ""WHAT" must be demonstrated to prove compliance," then they do not belong in the REOP field, nor anywhere else were they would convey a legal requirement.

2) ASSESSMENT OF THE SIGNIFICANCE OF REGULATORY UNCERTAINTY
NRC's CNWRA project management staff agree that there may be risk in exercising the mainstream PA development process when encountering regulatory uncertainty. We furthermore agree that where there is a need to reconcile uncertainties, in order to permit the PA analysis to proceed, this reconciliation must be done expeditiously.

In this regard, it would be desirable for the Center to be able to employ the Decision Support System (chapter 19 of the Center QA manual) or some other decision making apparatus that would help to judge the significance of the respective uncertainties in terms of potential delay to PA development. This would help to identify those uncertainties which require NRC immediate attention.

It would also be desirable for the Center to report on those uncertainties for which it considers "high risk." Furthermore, it would be equally desirable to have the Center report on those uncertainties it considers low or marginal to keep NRC's staff appraised of developments in this area.

To support this recommendation, we would like to have ten (10) working days to review and comment on those regulatory uncertainties you consider "high-risk" so that we might advise you on how to proceed with the analysis. Absent a response, you will proceed with the analysis based on your recommendation.

3) For low-risk uncertainties and high-risk uncertainties reviewed by NRC, PURL inputs are to be PA mainstreamed along with REOP's for the existing regulatory requirement not affected by the uncertainty.

4) As previously stated, PURL's are to be limited to those which the analyst considers could be best handled by changing the language of the rule but is not expected to include a judgement regarding resources, risk preferences, or time which are NRC's decision making responsibility.

Other uncertainties, not to be resolved by PURL's, still require the identification of an uncertainty reduction methodology. Depending upon what is subject to uncertainty (e.g. the regulatory requirement, REOP's, CDM's, and/or IR's), the URM's will be limited to the uncertainty itself and its subordinate components.

5) SUGGESTED APPROACH
The five-step approach is appropriate with the following modifications:

Step 2: The Center will use the weighting factors for the major milestone R8 analysis and report, as may be subsequently updated by NRC and the Center.

Step 3: The Center will recommend, based on the outcome of step #2, those high-risk uncertainties requiring NRC review and allow NRC ten days for review and comment.

Step 4: After ten working days, the Center will implement its recommendation, unless redirected by NRC.

QUESTIONS RE REORIENTATION OF EP AND NR PROCEDURES 2/15/89

1. Proof of compliance with a Regulatory Requirement must include (1) the demonstration that the waste management system (or specific components) satisfy the requirements of the Regulatory Requirement (the Regulatory Elements of Proof) and (2) the demonstration that the evidence offered is technically adequate (Technical Components of Proof). Taken together, Regulatory Elements of Proof and Technical Components of Proof define "WHAT" must be demonstrated to prove compliance. A crucial part of the PA concept is the hierarchical definition of the logical interrelationships of "WHAT" is required for proof of compliance. It is highly desirable to provide that definition in a single, integrated logic structure. This provides the visibility necessary for clear understanding and application, and makes possible a consolidated input to the Format and Content Guide. To satisfy the above, Technical Components of Proof need to be contained in the same field as the Regulatory Elements of Proof with, of course, a means to clearly distinguish between the two. We wish to verify that this approach is acceptable to the NRC.

2. In the presence of a Reg UN, there are varying degrees of risk in pursuing the mainstream PA process. In some cases, risk may be unacceptable to NRC (e.g., Compliance Determination, Info Reqm'ts, cost and schedule estimates based on current GWTT rule could be valueless). This suggests the need for an early judgement of the significance of each UN, either by NRC or by the Center or by the Center with NRC review. How can this judgement of UN significance be expeditiously made?

3. If a PURL is prepared, is the development of PA process mainstream inputs to be based on the PURL or on the existing rule?

4. We understand that a PURL is limited to the section(s) that are expected to be impacted by rulemaking. Is this correct?

5. Suggested approach to avoid perception that the Center is making decisions re specific UN Reduction method (e.g., rulemaking): [Note that the solution to question 2, above, could be included in the following approach.]

For High risk

1. The Center would ..
   a. Define the desired outcome of the uncertainty reduction,
   b. Identify reasonable alternative methods for achieving that outcome,
   c. Summarize the merits and drawbacks of each alternative, and
   d. Assess the attributes of the UNCERTAINTY (e.g., Importance, Time constraints, Durability, Impact on Site Characterization),
2. The NRC would assign weighting factors and establish the ranking of the UNCERTAINTY relative to other open uncertainties,
3. The NRC would select the reduction method to be used taking into consideration the nature of the UNCERTAINTY and its ranking,
4. The Center would complete the plan for the conduct of appropriate NR activities [i.e., complete sections c through f of Field 39 (process step 15) and process steps 16 - 22].

Is this approach acceptable? If so, how can we ensure expeditious completion of items 2 and 3?