

NOV 25 1988

WSEI A3,A4,E17 COMMENTS

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Mr. Allen R. Whiting, Director  
 Systems Engineering and Integration Department  
 Center for Nuclear Waste Regulatory Analyses  
 P.O. Drawer 28510  
 6220 Culebra Road  
 San Antonio, Texas 78284

Dear Mr. Whiting:

SUBJECT: COMMENTS ON CNWRA'S MEETING REPORT WITH REGARD TO PROGRAM  
 ARCHITECTURE DEVELOPMENT MILESTONES A3/A4 AND E17 PROGRAM  
 ARCHITECTURE INPUT

We have received the subject document you recently transmitted. As stated, the meeting report corresponds to the joint discussion conducted between NRC and the CNWRA at NRC headquarters on November 1, 1988. The purpose of this meeting was to share with you some of our preliminary comments with regard to the regulatory requirement topic example to be used to demonstrate fulfillment of the "proof-of-system" milestone R7.

Prior to this meeting, I transmitted to you NRC's reaction (correspondence dated October 28, 1988) regarding the selection of the E17 example as the "proof-of-system" example. In this correspondence and at the time of the meeting we communicated to you our concerns that the E17 example did not completely fulfill milestone A3 as "information" requirements were lacking, and the A4 requirements were not addressed. Although it would be desirable to have an example that demonstrates as many of the 22 WSE&I process steps as possible, we concluded during the meeting that no regulatory requirement topic could be expected to demonstrate all of the attendant PASS data fields. It was conceded both in the meeting and earlier in the "Conceptual Requirements Document" for the December deliverable (circa June, 1988) that it may be necessary to select a second regulatory requirement topic example in order to achieve the requirements of milestones A3/A4. Regulatory requirement topic "E36" (entitled "Structures, Systems, and Components Important to Safety -- Protection Against Natural Phenomena and Environmental Conditions.") was proposed by Wes Patrick as a possible supplement to "E17" for the purposes of achieving the "intent" of the requirements for milestones A3/A4. This proposal was qualified, though, owing to concerns of how the analysis of the E36 regulatory requirement topic might impact on the Center's existing production schedule. However, it was also noted that this approach, while addressing the automated data processing features of the PASS database, does not fully illustrate the "dynamics" of proceeding from one WSE&I process block to another and therefore could have significant impact on the "proof-of-system."

The meeting report you transmitted captures most of the discussion in the preceding paragraph as well as some additional points of common interest. However, in comparing this report with our notes of the meeting, we have found that there are a few "pertinent points" that require not only elucidation but additional clarification. We hope you find that these comments contribute constructively to our joint goal of implementing a Program Architecture. The discussion points are as follows:

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#### Truncation of Program Architecture Development Process

During the subject meeting, considerable discussion centered upon the approach described in TOP-001-02 to be used to analyse regulatory requirements, e.g. E17. In implementing TOP-001-02, the 22-step WSE&I process for developing the Program Architecture is being stopped shortly after a "regulatory uncertainty" is encountered (i.e., a partial completion of process block no. 8, and no completion of process block no.'s 5, 6, 7, 9-14, and 16-22). There are several concerns with regard to this approach in that 1) it is in apparent conflict with the 22-step WSE&I process described in TOP-001 (revision 1); 2) it appears to curtail further development of the Program Architecture until the "regulatory uncertainty" associated with any set of "regulatory requirements" is resolved; and 3) it could adversely affect the collection of information important to the completion of Program Architecture development milestone R9.

Section 5.4.2 of TOP-001-02 (page 5) specifies that "elements of proof," process block no. 3 of the 22-step WSE&I process, will not be developed if a "regulatory uncertainty" is encountered. As applied to the E17 example, the implementation of this section of the TOP has effectively resulted in "truncating" the 22-step WSE&I process until the uncertainty is resolved. This particular procedure is not consistent with the WSE&I process diagram, as shown on page 3 of TOP-001. In particular, a decision point for resolution of uncertainty is not indicated. Furthermore, when truncating the process, there is no indication of how the development of the Program Architecture proceeds. How the center will proceed with the developing Program Architecture therefore needs clarification when reaching such a point.

Truncating the WSE&I process when encountering a "regulatory uncertainty," could have serious implications for the development of the Program Architecture. First, if resolution of the "uncertainty" is delayed, for as much as two years as in the case of a rulemaking, important information concerning "compliance determination methods," "information needs," "technical uncertainty," and "DOE-State/Tribe issues" may not be collected. This problem is further exacerbated in that when an "uncertainty" is encountered in one "element of proof," the WSE&I process is stopped for all other related regulatory requirements (or "elements of proof") even though they were not subject to the same "uncertainty." We question whether this approach is appropriate. Second, by following this approach, information may not be collected that could be important to the completion of Program Architecture development milestone R9 whose purpose is to recommend areas of staff emphasis in the review of the Yucca Mountain Site Characterization Plan (SCP). It is generally felt that "information needs," as described by the WSE&I process, are not only important in assessing DOE's SCP but also in developing "rulemaking" topics (e.g., Program Architecture development milestone R8).

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Having discussed these points with you, several questions thus remain unanswered. How will the Center proceed after encountering a "regulatory" or "institutional uncertainty?" Will an NRC decision point be required to continue the WSE&I process after it has been stopped because of an "uncertainty," and will there be sufficient information for NRC to make a timely decision? How will the WSE&I process diagram and applicable TOP's represent this process? Will the process that has been followed by the Center to date affect the timing or the quality of the R8 and R9 milestone deliverables?

#### Regulatory Requirement Topics

In the development of the Program Architecture, regulatory requirement topics clearly represent the foundation upon which the WSE&I process is based. However, it appears that the procedure for developing the "suite" of regulatory requirement topics needs to be documented in order for us to determine why regulatory requirements have been added or omitted from any particular topic, which regulatory requirements are driving the program vis-a-vis the Program Architecture, and the relationships between the respective regulatory requirements.

We believe this documentation would correspond to the "analysis" that was performed by the Center in WSE&I process block no. 2. This information when added to the "note" field along with the restructuring of the of the "note" field itself, as stated in item no. 9 of your report, would provide the necessary insight into your analysis.

#### Elements of Proof

In section 5.4.2 of TOP-001-02 (page 5), it was our impression that if an element of proof existed in the regulation and thus could be attributed to specific regulation section [number], then it would not be "postulated." Again, if a regulatory requirement and its attendant "element(s) of proof" were judged to be adequate as written, then we would not expect to see "postulated" elements of proof." Consequently, we would have expected that the remaining steps in the 22-step logic stream would be exercised for those non-postulated "elements of proof."

In closing, these issues along with the limited information provided to date regarding Program Architecture (PA) development activity have raised concerns among our staff with respect to the ability of the PA database to fully support future Center milestones at this time. If there are any problems, particularly if they impact on the December deliverable, please inform me immediately and indicate your recommended course of action.

Sincerely,

**Original Signed by**

Philip M. Altomare  
Program Element Manager  
Waste Systems Engineering  
and Integration

OFFICIAL CONCURRENCE AND DISTRIBUTION RECORD

MEMORANDUM FOR: Allen R. Whiting, Director  
Systems Engineering and Integration Department  
Center for Nuclear Waste Regulatory Analyses

FROM: Philip M. Altomare  
Program Element Manager  
Waste Systems Engineering and Integration

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