



November 8, 2000

Mr. Michael T. Bugg  
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Mail Stop O-6F2  
Washington, DC 20555-0001

**RESPONSE TO INQUIRY ON NIRMA TG16-1998, "SOFTWARE CONFIGURATION MANAGEMENT AND QUALITY ASSURANCE"**

Dear Mr. Bugg:

The Nuclear Information and Records Management Association (NIRMA) is pleased to provide a response to your recent inquiry.

Your inquiry is stated, as follows:

"Guidance provided in TG16-1998, Nuclear Information and Records Management Association (NIRMA), states that records retention is not applicable (N/A) for safety related software documentation. Someone thinks that the guidance directly contradicts 10 CFR 50, Appendix B requirements. Question: Could you provide a clarification on why the documentation for Level 1 systems is not applicable?"

NIRMA's Response

10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants", establishes the quality assurance requirements for the design, construction and operation of those structures, systems, and components that prevent or mitigate the consequences of postulated accidents that would cause undue risk to the health and safety of the public. Further, 10CFR50, Appendix B, "Introduction" states "The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems or components..." Additionally, 10CFR50, Appendix B, Criteria IV, "Procurement Document Control" specifically requires that "Measures shall be established to assure that applicable regulatory requirements, design basis, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment and services..." Finally, 10CFR50, Appendix B, Criteria XVII, "Quality Assurance Records" states "Sufficient records shall be maintained to furnish evidence of activities affecting quality."

NIRMA Technical Guideline TG16-1998, "SOFTWARE CONFIGURATION MANAGEMENT AND QUALITY ASSURANCE" has within its scope any information management system. However, NIRMA TG16-1998, Appendix A, specifically is concerned with electronic records systems. Appendix A represents a graded approach for maintaining software QA documentation of an electronic records system. Quoting directly from TG-16, 1998:

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## "APPENDIX A

## GRADED APPROACH TO ELECTRONIC RECORDKEEPING SYSTEMS

The following represents a graded approach to software QA for electronic records systems. Terms, and their definitions, may vary from facility to facility so care must be applied to clearly define what is incorporated in the specific documents/stages of development."

While System Levels Two, Three and Four as indicated in Appendix A do not, in themselves, design, construct or operate safety related structures, systems or components, they do identify the location or source of, or contain, QA records that reflect such "design, construction and operation of those structures, systems and components". Therefore NIRMA, for the purposes of TG16-1998, Appendix A electronic records systems, has defined such systems as falling under the requirements of 10CFR50, Appendix B including Criteria IV and XVII. Accordingly, NIRMA TG16-1998 indicates appropriate requirements to "assure adequate quality are suitably included or referenced in the documents for procured material, equipment and services..." and that "Sufficient records shall be maintained to furnish evidence of activities affecting quality."

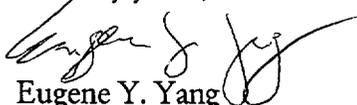
Conversely, Level One systems, by definition and if properly classified, do operate safety related structures, systems or components; however they do not identify the location or source of, or contain, QA records. Therefore, NIRMA, for the purposes of TG16-1998, Appendix A electronic records systems, has defined such systems, while falling under the requirements of 10CFR50, as N/A (Not Applicable) from an electronic records perspective. Therefore, those systems themselves, and not the system documentation requirements, are N/A. This is clearly stated in the notation quoted above from TG16-1998, Appendix A. This, however, does not preclude the use, or applicability, of system documentation requirements identified in other guidance documents with respect to Level One, safety-related, systems which do not generate, maintain or store QA records.

Additionally, the Nuclear Regulatory Commission's Regulatory Information Summary (RIS) 2000-18 itself states "... The scope of the NRC's acceptance of these four NIRMA technical guidelines is only for managing electronic quality assurance records." which itself precludes the inclusion of Appendix A Level 1 systems due to their lack of involvement in the generation, maintenance and storage of QA records.

Therefore, based on the points detailed above, NIRMA believes there is no conflict with, or omission of, appropriate requirements identified in 10CFR50, Appendix B in NIRMA TG16-1998, Appendix A.

Please feel free to contact me should you have further questions regarding this clarification.

Sincerely yours,



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President

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