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**Subject: Regulatory Information Summary 00-18, "Guidance on the Management of Quality Assurance Records on Electronic Media"**

On March 30, 2011, the NIRMA Regulations and Information Management Business Unit (RIMBU) held a meeting at the NRC headquarters. During that time, we had the opportunity to discuss a possible revision to Regulatory Information Summary (RIS) 00-18 with NRC staff from the Office of New Reactors (NRO), the Office of Nuclear Reactor Regulation (NRR), and Office of Information Services (OIS). We were encouraged by the discussion and it was determined that we should pursue a direct request to your respective Offices.

RIS 00-18 endorses the use of four (4) NIRMA Technical Guidelines (TGs), as follows:

- NIRMA TG-11, "Authentication of Records and Media"
- NIRMA TG-15, "Management of Electronic Records"
- NIRMA TG-16, "Software Quality Assurance Documentation and Records"
- NIRMA TG-21, "Required Records Protection, Disaster Recovery, and Business Continuation"

RIS 00-18 refers to the 1998 versions of these TGs. Since that time, we have continually reviewed and updated these versions; these updates reflect the evolution that has occurred in records management best practices and the deployment of information technologies.

The concern is, that since the RIS 00-18 refers specifically to the 1998 versions of the TG's, the utilities that are committing to an electronic records program (and the use of the various technologies), feel that they can only go with the guidance provided in the 1998 versions, hence using philosophies, perspectives, and guidance that are essentially from the early- to mid-90's.

Based on the ever-changing technology environment, and the lessons learned throughout the industry and enterprise content management (ECM) technology improvements since the 1990's, NIRMA embarked on these updates; the 2011 versions represent a "best of class" perspective on the use of electronic technologies for document control, records management, and data administration.

YE02  
YE03  
YE04

This directly affects not only the legacy reactor sites, but also those utilities that are embarking on new plant construction. The new construction projects are striving to do everything electronically, beginning with the ESP/COL submittals to the NRC, followed by the electronic exchange of documents and information between themselves and their EPC's during design and construction, and then eventually the transfer of baseline as-built information when they enter the operations and maintenance phase. At this point they are challenged in their ongoing efforts to become much more efficient and effective in doing business, because of the use of outdated (1998) guidance.

We would like the NRC to consider, either: a) issuing a new RIS on the subject of electronic records management, b) modifying the existing RIS to accommodate the use of any version of a cited TG, or c) provide some other means to communicate to industry that there are better and more accommodating guidance/standards from NIRMA available for electronic records management.

Therefore, NIRMA is respectfully requesting that you perform a review and ultimately endorse the revisions of the four affected Technical Guidelines (TG's). Please find attached further information to assist in your review.

NIRMA is a professional society dedicated to the advancement of information management in highly regulated industries. It consists of information management and information technology professionals from nuclear plant design and nuclear power generating facilities, DOE weapon sites, and DOE laboratories. NIRMA is an ANSI standards development organization. For example, we developed the ANSI/NIRMA CM 1.0-2007, "Guidance for Configuration Management at Nuclear Facilities". NIRMA has been in existence since 1977 and will be celebrating its 35th anniversary this year.

Sincerely yours,



Linda Torunski  
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cc: Mr. Thomas M. Boyce  
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J. Hannum, Executive Director, NIRMA

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Attachment 1

## **ATTACHMENT 1 - BASIS FOR REQUEST**

In 1998-99 time frame, NIRMA petitioned the NRC to evaluate the adequacy of four NIRMA Technical Guidelines (TGs) which, when collectively applied by a Licensee, would be an acceptable means for managing Quality Assurance Records in electronic media. This was proposed as an alternative to Generic Letter (GL) 88-18, "Plant Record Storage on Optical Disk" which confines storage of Quality Assurance Records to optical disk platters. RIS 00-18 (issued October 23, 2000) was issued by the NRC based on the NIRMA TGs (and related industry standards) which were published in 1998.

NIRMA went through an major effort in reviewing and updating the original four TGs during the period from 2006 to 2009. Further updates were made during an affirmation review of the four TGs during the March 30-31, 2011 Regulations and Information Management Business Unit (RIMBU) meetings. These updates reflect advances in technology, enhancements in managing electronic records and new business issues, e.g., digital rights management for further control in the use and distribution of records.

To put this into context, information technologies are constantly evolving. In the 1995-1998 timeframe, the dominant desktop operating system was Windows 95; Netscape was the dominant web browser; WordPerfect was the dominant word processing application. The NRC had just embarked on Electronic Information Exchange and was in the implementation of ADAMS. Adobe Corporation had introduced the Portable Document Format (PDF) earlier in the decade and was introducing Acrobat 2.0 (PDF specification 1.1). Electronic document management implementations by utilities were fragmented, document-type-based endeavors, primarily an indexing database, but still pointing to hardcopy/film, with pen-and-ink signatures ("1<sup>st</sup> generation electronic document management systems"); there was a heavy client/server approach to document management systems

Now, in 2011, the dominant desktop operating system is Windows XP/Windows 7; the dominant web browser is Windows Internet Explorer; Microsoft Word 2007 is the dominant word processing application, with a shift to eXtended Markup Language (xml) capabilities. Tactical distributed collaboration and storage applications, such as SharePoint have emerged; Enterprise content management (ECM) are being deployed for single plants and "fleets", that include functionality to support multi-document types, electronic workflows, and electronic signatures. ECM vendors have migrated technologies to multi-tier, web-based architectures. PDF is the dominant "generic format" (Acrobat 9/10, PDF specification 1.7), and to such an extent that an international standard is established for an archival form of PDF (ISO 19005, PDF/A).

At the nuclear power generating stations, several operating plants are using optical systems but are interested in moving to full magnetic storage due to:

- M&O costs to stay compliant with requirements of GL 88-18;
- Maintenance & support of the older technology; and
- Expanded business requirements related to managing electronic records.

New nuclear plant owner/operators have committed to the RIS in the Quality Assurance Program specified in their COLA, but some want to adopt the later versions of the NIRMA TGs to be aligned with and positioned to use newer technologies. NQA-1 revisions are looking into management of Quality Assurance Records in electronic media and members of the NQA-1 Records sub-committee have indicated an interest in adopting the new TGs as part of a future revision.

Thus, the nuclear industry (power generators, DOE facilities) are challenged in the "existing" electronic records environment in that RIS 00-18 identifies specific revisions (by date) of the four TG's. Existing operating plants desiring to adopt the new TG's are then blocked from doing so by their QA departments based on:

- The QA section of their FSAR commitments to the RIS, and

- The RIS points to “specific revisions” so the new TG’s cannot be adopted.

New plant owner/operators’ records management staff, who are committed to the RIS via their COLA, cannot deviate from the specific TG revisions per their QA departments, and thus are hampered in being able to take advantage of emerging technologies. Existing plant Licensees can petition the NRC via an FSAR change request and SER to adopt the new revisions, but that essentially deals in an isolated case and does not best serve the industry as a whole.

The following table provides a high-level comparison of 1998 version of the TGs versus the recent updates. The intent is to provide guidance for the review.

NIRMA TECHNICAL GUIDELINES COMPARISON TABLE

TG TITLE	COMPARISONS		COMMENTS
TG-15 "Management of Electronic Records"	Comparison of 1998 vs 2009 Revision		This TG is the "mother guidance", as it explains the entire electronic records program. The revision provides more detail on electronic systems, program requirements, and general information for new users. Addresses issue of format sustainability, by various file types. More complete references.
	<p>1998 – 17 pages</p> <p><i>"What"</i></p> <p>System Requirements ERM Program Creation/Approval/Use</p> <p>Storage and Maintenance Retention</p> <p>Attachment A – definitions (28)</p>	<p>2009 – 51 pages</p> <p><i>"How-To"</i></p> <p>24 definitions Lifecycle Approach: Creation thru Destruction Includes guidance on E-Transfer, E-Receipt, and E-Authentication</p> <p>Includes general guidance on Security, Disaster Planning, and Software Quality Assurance</p> <p>Appendix A – ERM Program Appendix B – Format Sustainability Appendix C – Format Transformation Appendix D – Content Rights Management</p>	
TG-11, "Authentication of Records and Media"	Comparison of 1998 vs. 2007 Revision		Not that much difference; more emphasis placed in TG-15.
	<p>1998 - 6 pages</p> <p>Record Media Records Authentication - Hardcopy - Electronic Media Records Conversion - Scanning Systems Media Certification - Hardcopy - Microform - Electronic - Labeling - Magnetic Media Testing and Inspection</p>	<p>2007 – 5 pages</p> <p>Record Media - Must meet or exceed the retention period - Media regeneration/records migration Record Authentication - Hardcopy - Electronic - Media Authentication Records Media Conversion Conversion Systems Record Series Processing - Hardcopy - Microform - Electronic (refer back to TG-15)</p>	
NIRMA Technical Guideline TG-16	Comparison of 1998 vs. 2008 Revision		Moved from directly dictating SQA definition to the support and role of IRM in SQA activities.
	<p>1998 - 12 pages</p> <p>"Software Configuration Management and Quality Assurance"</p> <p>Covers software used for both QA and non-QA electronic information Addresses SQA source documents</p> <p>Program Organization</p> <ul style="list-style-type: none"> <li>o Project Management</li> <li>o Information Services (IT)</li> </ul> <p>Software Lifecycle Documents System Configuration Management SQA Documentation for QA Records Virus Protection Appendix A – Graded approach to electronic recordkeeping systems</p>	<p>2008 – 13 pages</p> <p>"Software Quality Assurance Documentation and Records"</p> <p>Covers software used for both QA and non-QA electronic information Addresses documentation and records requirements related to SQA and CM</p> <ul style="list-style-type: none"> <li>o Critical areas of responsibility for IRM</li> <li>o Core set of requirements and controls</li> <li>o Identifying application-related documentation that provides evidence of appropriate quality measures have been applied</li> </ul> <p>SQA Policy SQA Program Software Lifecycle Management Retention Requirements Does not address data management</p> <p>Appendix A – Typical SQA Process Flow Chart Appendix B – Typical Graded approach to SQA</p>	
NIRMA Technical Guideline TG-21	Comparison of 1998 vs. 2006 Revision		Broader (all formats and media; supporting business continuation) and more detailed to give better guidance on the major aspects of disaster response and recovery.
	<p>1998 - 4 pages</p> <p>"Electronic Records Protection and Restoration"</p> <p>Disaster Support Team</p> <p>Disaster Recovery Plan Implementing Policies and Procedures Disaster Recovery Infrastructure System Backup Testing and Maintenance</p>	<p>2006 – 9 pages</p> <p>"Required Records Protection, Disaster Recovery, and"</p> <p>Records Disaster Plan and Business Continuation Plan – includes all formats and media</p> <p>Disaster Response Team Disaster Response Plan</p> <ul style="list-style-type: none"> <li>o Prevention Planning</li> <li>o Disaster Response and Recovery</li> <li>o Post-Disaster Planning</li> </ul> <p>Data and systems protection – records recovery priorities Importance of forewarning Testing and maintenance Appendix A – Disaster Response Planning – Recovery Options for Water-damaged collections</p>	