

ANI Response to NIRMA's Comments
Re: ANI Bulletin 80-1A Rev. 6 (Draft)

ANI has evaluated the compilation of comments provided by NIRMA constituents regarding ANI Information Bulletin 80-1A Rev. 6 (draft). The comments were comprehensive and thorough and will result in a better document. We much appreciate the time and effort that went into their formulation. We have incorporated the majority of the comments into the Bulletin. Due to our need to retain records critical to third party nuclear liability claims investigation, evaluation and defense of our insureds; we are not able to incorporate all of the comments. For ease of review, following are the NIRMA comments and ANI's response.

NIRMA Item #1 (Page 3, Section 2)

Current text: Contractor Employees (The term "Contractor Employee" includes all non-utility employees, short term or long term, seeking unescorted access.)

Comment: Please define "non-utility."

ANI Response to NIRMA Item #1

We agree with your comment and in order to clarify this issue, the definition of a contractor employee will be revised as follows: Contractor Employees (the term "Contractor Employee" includes those individuals not in the employ of the insured(s) named in the nuclear liability insurance policy, short term or long term, seeking unescorted access.)

NIRMA Item #2 (Page 4, Section 1.4)

Current Text: Tests, answer sheets and acknowledgements of training should carry the signature of the individual trained as well as the date of the training. Electronic signatures may be used for CBT testing.

Comment: Insert after "Electronic signatures" the following text "or other form of electronic authentication"

ANI Response to NIRMA Item #2

ANI concurs with the proposed wording. It will be incorporated into Rev. 6.

NIRMA Item #3 (Page 5, Section 2.1)

Current text: Special instructions given to such persons should be documented.

Comment: Please clarify “special instructions”

ANI Response to NIRMA Item #3

The special instructions to Visitors and Escorts are described in ANI Engineering Inspection Criteria, Section 2.0, Rev. 5, *General Employee Training*. The specific criteria are noted below.

2.0.13.1 As a minimum, escorted individuals who enter the RCA should receive a radiological briefing (e.g., dose rates, contamination levels, postings, etc.).

2.0.13.2 If escorted individuals are required to enter a contaminated area, the visitor’s work experience should be evaluated. If the escorted individual has no dress-out experience, dress-out training should be provided. If the escorted individual has satisfactory dress-out experience, this criterion may be waived. The evaluation and training (if required) should be documented.

2.0.14.1 Escort instructions should include: number of visitors allowed per escort, line-of-site control, RCA access control requirements (e.g., dosimetry issue, radiological briefing, RWP use, etc.), Contamination Area and Airborne Area restrictions, emergency evacuation requirements, etc.

2.0.14.2 These instructions should be provided during the normal GET training; however, as a minimum they may be provided via “handout” prior to performing escort duties.

NIRMA Item #4 (Page 13, Section XI.1)

Observed: It is noted that this Section has been expanded to include all radioactive shipment records whereas the prior Bulletin restricted requirements to radioactive waste shipments.

Comment: Please clarify need for expanded records on non-waste shipments.

Observed: Record #1 of this Section includes “Surveys of transport vehicles and their loads.”

Comment: These surveys are not required under DOT or NRC for all shipments. Please include basis for the requirements for these additional records.

ANI Response to NIRMA Item #4

The ANI Facility Form Policy provides coverage for insured radioactive waste and radioactive material shipments from the insured facility to any other location; but only until the material is removed from the transporting conveyance. Should a claim arise alleging bodily injury or property damage as a result of a radioactive material shipment, ANI would need the surveys and shipping records (radionuclides, activity, etc.) to investigate, evaluate and defend the claim.

NIRMA Item #5 (Page 14, Section XIII.5)

Current text: HP logs containing radiological survey information, contamination events, radiological incidents, release information, radiation monitor information, event descriptions, etc. (e.g., HP Office Log, Shift Technician Log, etc.).

Comment: Please define “HP” – Hot Particle or Health Physics?

General Note: Throughout the document, please define all abbreviations / acronyms at the time of their first appearance in the document or include all of them in a designated section at the end of the document.

ANI Response to NIRMA Item #5

We agree with your comment. It is ANI’s practice to define all abbreviations / acronyms at the time of their first appearance in the document. This was done for “HP” on page 5, Section 1.6.7. ANI will review the Bulletin to ensure all abbreviations / acronyms are appropriately defined.

NIRMA Item #6 (Page 14, Section XIII.6)

Current text: Quality assurance audits of TLD vendors.

Comment: Some facilities have considered NVLAP qualification sufficient to document QA requirements for these vendors and have not performed independent audits. Please clarify the need (or expectation) that QA audits be performed on TLD vendors.

ANI Response to NIRMA Item #6

ANI concurs. The Bulletin will be revised to read: Quality assurance audits and/or NVLAP audits of TLD vendors.

NIRMA Item #7 (Page 15, Acceptable Storage Media, 2nd paragraph)

Current text: When transferring records from the original hardcopy to an acceptable alternate media, the facility must ensure the final format is capable of producing clear and legible copies for the duration of the recommended retention period....As such, when transferring records from the original media to an acceptable alternate media, administrative controls are essential (e.g.....etc.).

Comment: Line 2 – Insert after “final” the word “record”

Comment: Line 2 – Insert after “capable of” the following text “being retrieved and”

Comment: Line 5 – Insert after “alternate media” the following text “(or migrating electronic records from legacy electronic media to another electronic media)”

ANI Response to NIRMA Item #7

ANI concurs with each of the above noted comments. These comments will be incorporated into 80-1A, Rev. 6.

NIRMA Item #8 (Page 16, First Bullet, 2nd sentence)

Current text: IT and Records Management personnel should be cross-trained on one another’s responsibilities.

Comment: Cross-training should be clarified with respect to intent and degree of detail. This requirement should not be construed such that personnel within these two (2) organizations must be able to perform all the work activities of either group.

Comment: Suggest text change: Delete “on one another’s responsibilities” and insert after “cross-trained” the following text “such that personnel are familiar with the general duties and responsibilities of one another’s positions.”

Comment: Suggest consideration for adding the following as another bullet in this area “Effective management of electronic records demands coordination among three different management groups within an organization (IM, IT and RM).” This principle is taken from NIRMA Technical Guideline TG-15, Management of Electronic Records.

ANI Response to NIRMA Item #8

ANI concurs with the above noted comments. The two suggested text changes will be incorporated into 80-1A, Rev. 6.

NIRMA Item #9 (Page 16 – Second Bullet)

Current text: Document Control should use an “Electronic Vault” to receive electronic files from the document originator. Interim storage concerns should be addressed (e.g., Where do documents reside before being downloaded to the final storage media? How long do they reside in interim storage?)

Comment: Line 1 – Replace “Document Control” with the following text “Document Management or Records Management”

Comment: Lines 1&2 – In lieu of requiring an “Electronic Vault” for the initial receipt of electronic files received from document originator, suggest that a facility could use an “acceptable temporary storage location having file security and restricted edit capabilities, e.g., a restricted folder on the Local Area Network.” Interim Storage concerns should be addressed as noted. Consider incorporating the temporary storage option into this section of the bulletin.

ANI Response to NIRMA Item #9

ANI concurs with the above noted comments. The two suggested text changes will be incorporated into 80-1A, Rev. 6.

NIRMA Item #10 (Page 16 – Special controls section, First & Second Bullets)

Current text:

- The e-records should be safeguarded to ensure access to the data is controlled to prevent unauthorized manipulation.
- An audit trail should exist for the generation and transfer of e-records.

Comment: If there is an “authorized manipulation,” suggest the audit trail include documentation of any changes to the e-record after it is received from the document originator.

Comment: After the second bullet, consider adding the following sentence “Any corrections, changes or additions should be documented on the electronic record.”

ANI Response to NIRMA Item #10

ANI concurs with the above noted comments. The suggested text change will be incorporated into 80-1A, Rev. 6.