



The NELAC Institute (TNI) Quality Systems for Radiochemistry Expert Committee  
Meeting Minutes

**The Quality Systems for Radiochemistry Expert Committee of The NELAC Institute (TNI) met on October 26, 2012 via teleconference.**

The committee meeting commenced at 2:00 ET.

**Participants:** Bob Shannon, Sreenivas Komanduri, Marty Johnson, Dave Fauth, Tom Semkow, Carolyn Wong, Keith McCroan, Todd Hardt, Nile Ludtke, Larry Penfold, Terry Romanko, Richard Sheibley, Ken Jackson (TNI)

The agenda was distributed by email along with the following documents:

1. Decision-Making Rules for TNI Quality Systems for Radiochemistry Expert Committee Operations
2. Discussion on TNI Batches-Senkow 10/23/12
3. The NELAC Institute (TNI) Quality Systems for Radiochemistry Expert Committee Meeting Minutes (9/28/12)

Ken Jackson also distributed the following TMI standard operating procedures by email:

1. SOP 2-100 Revision 1.1 Procedures Governing Standards Development
2. SOP 2-101 Revision 1.0 Procedures for Expert Committee Operations

Prior to the meeting, Ken Jackson covered the SOPs governing group dynamics. In SOP 2-100, Ken emphasized section 1.1 Purpose and its connection to OMB Circular A-119 that defines the attributes of a consensus standard body and its members. Section 2.3.2 provides the criteria for balance of interests among committee members. Section 3.0 describes conduct of committee business with a meeting quorum of 50% and 2/3 voting on important issues and majority on lesser important topics. Ken indicated that he would be available to help word any notifications of proposed standards. He pointed out that the general public can participate but they need to contact the committee chairman to receive meeting notices. Section 5 on Standards Development is being revised by the Corrective Action committee. It is important to understand this section and also Section 6 on appeals that is required since TNI is affiliated with ANSI. Ken also indicated that TNI could provide meeting travel funds.

In SOP 2-101, Ken emphasized the duties of expert committees in Section 2.1.1 and voting in Section 2.3.1. Section 2.4 provides information for joining committees. Our members who have not joined were requested to join and nominate themselves for this committee (TNI Chair then can approve membership as long as committee balance is maintained-this is a formality as we are listed on the committee charter). Members can only be members of one expert committee (Section 2.4.4). Member terms of appointments and meeting attendance requirements are explained in section 2.5. Ken covered committee leadership (section 2.6) and the scheduling of meetings and issuing of minutes (section 3.0).

When questioned, Ken indicated that temporary interim amendments are reserved for major errors that need corrected/retracted before the next revision can be prepared and issued.

## **Agenda**

1. Establish Voting Rules
2. Election of Chair
3. Minutes Approval (retroactive)
4. Reminder to join TNI and submit committee application
5. Conference Call Scheduling

The meeting was called to order.

The voting rules issued by email before the September and this meeting were approved unanimously (no abstentions). See Attachment 1.

Bob Shannon was then nominated for committee chairman. No other members expressed interest in the position. Bob was unanimously elected (no abstentions).

For the Vice chair position, Tom Semkow indicated interest and was then nominated. He was also elected unanimously (no abstentions).

The meeting minutes from past meetings (June 29, July 27, and August 24) were retroactively approved as issued (unanimous assent - no abstentions). See Attachment

The meeting minutes from September 28 were then approved as issued (unanimous assent - no abstentions). See Attachment 3.

The committee is at 80% for TNI membership and committee membership approval. Those in the remaining 20% were asked to complete their membership and committee applications ASAP.

The committee discussed when the November meeting should be scheduled. There were conflicts with all the dates suggested so Bob will suggest several dates for November and December meetings in an email to the committee and will then pick dates. Scheduling dates for 2013 meetings should be a simpler task.

The remainder of the meeting was spent discussing the batching memo (Discussion on TNI Batches-Semkow 10/23/12). The memo on batching defined batch, preparation batch, and analytical batch. Tom's concern is that labs have difficulty utilizing their facilities effectively because of the 24-hr time requirement.

While commercial labs have an advantage in that they can charge a premium for expediting analysis, smaller labs are at a competitive disadvantage relative to larger labs who can more quickly construct larger batches. Government labs have difficulty obtaining adequate resources and often sacrifice quick turnarounds in order to increase batch sizes. Recognizing the difference between prep and analytical batches and how we design our quality systems for each type are keys. Bob's concern is that we will

have difficulty making a change to the batch concept that is common across all other areas of NELAC for operational reasons alone. Instead, we need to ensure that any changes will be technically defensible/logical, and that they will not result in a net loss of quality, or different levels of quality for different tests. The extended discussion was not successful in identifying one or more possible solutions. Therefore, committee members were requested to prepare written opinions/suggestions that facilitate how the standard addresses this topic. Flexibility, clear interpretation (for laboratories, ABs and users), and clear and consistent quality control are key. The entire committee should review prior to the next meeting.

The chair requests that any comments be submitted at latest one week before the next scheduled meeting (TBD)

The meeting adjourned at 4:00 PM ET.

**Committee Action Items**

Suggested Dates for November and December meetings	Bob
TNI and committee submit membership application	Committee
Provide input on batching and path forward on batching	Committee

Respectfully submitted,  
David Fauth

**Attachment 1 – Decision Making Rules for Quality Systems for Radiochemistry Committee - as Considered and Adopted on 10/26/2012 Committee Conference Call**

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**Decision-Making Rules for TNI Quality Systems for Radiochemistry Expert Committee Operations**

<b>Type of Decision</b>	<b>Decision-Making Rule</b>
Meeting dates, times	Person-in-charge decides after discussion
Meeting adjournment	Person-in-charge decides after all business is conducted or allotted time expires
Meeting minutes approval	Request for approval by email to all committee members – changes approved if needed from email. No Vote
Meeting cancellations	Person-in-charge decides
Addition of TNIQS Committee Members	Two-thirds of committee must vote and simple majority vote
Removal of Expert Committee Members	Person-in-charge decides after discussion
Approval of Standards – any stage (including persuasive/non-persuasive votes)	At least two-thirds of committee must vote in the affirmative
Creation of a new subcommittee	Simple vote of attendees
Election of Committee Chair	Two-thirds of committee must vote and simple majority vote
Standard Interpretation Requests	Simple majority vote of attendees

## Attachment 2 – Minutes from Past Meetings – As considered and adopted in the October 26, 2012 Committee Conference Call

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**Date/time:** 9/28/2012 at 2:00 ET

**Participants:** Bob Shannon, Sreenivas Komanduri, Marty Johnson, Dave Fauth, Tom Semkow, Carolyn Wong, Todd Hardt, Nile Ludtke, Richard Sheibley, Terry Romanko,

The agenda was distributed by email along with the following documents:

1. Definitions for Quality Systems for Radiochem
2. Collected Comments for 20120924 Call
3. Committee Chair Requests-Quality Systems-214-215-08-31-12 updated 092812
4. QS Decision Rules
5. Link for Application as Committee Member (<http://www.nelac-institute.org/comm-app.php>)

### Agenda

1. Review and approve minutes (attached)
2. If Ken Jackson from TNI can be on the call, we will discuss organizational matters.
3. Continue review of Module Six
  - a. Consider proposed text on ICP-MS from Nile, Carolyn and Bob in collected comments (attached).
  - b. Take a quick look at definitions document – these are not meant as the beginning of a glossary, but rather as a living document for reference updating as we proceed. We can attack definitions as we work through the module, and step by step incorporate them into the standard.
  - c. Continue on with the review
4. Additional items
5. Set up next meeting

The minutes from the August 24 meeting were approved as issued.

Bob discussed the copy of the TNI Quality Systems voting rules that he sent via email. These are the rules being used by the Quality Systems Committee. They should work well for our purposes. He asked that members review these prior to the next meeting when we will formalize them.

Bob also discussed NELAC application. Everyone needs to join NELAC (if you have not done this already). Each committee member also needs to complete an online committee application at <http://www.nelac-institute.org/comm-app.php>. This is more a formality since we are all listed on the committee charter. We are also waiting for final, formal notification that we have been elevated from subcommittee status to committee. This will take place in 2-3 weeks when the Committee Charter is approved. If anyone has a strong desire to chair the committee please inform Bob.

Ken Jackson was not able to participate in the meeting today so Agenda Item #2 was skipped. Bob indicated that Ken is feeding him information on committee logistics.

The Quality Systems Committee sent two Standards Interpretation Requests (SIRs) to our committee (Document #3). In general, when we get SIRs, we need to be sure that our response only answers the question asked and is an interpretation of the standard and not an opinion; and that it is grammatically correct. SIR# 215 deals with the use of Monte Carlo techniques for gamma spectroscopy. The group decided that using Monte Carlo techniques runs counter to the requirement in 1.7.1 a) that *Instrument calibrations must be performed with reference standards that have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples. See sections 1.7.2.5 c) i) and 1.7.2.5 c) i) for requirements for calibration standards.*

Discussion followed about available software packages, DOE and NRC approval of Monte Carlo techniques, the use of standards and Monte Carlo techniques, geometry and density limitations with available standards, and code tuning for efficiency correction. The group response was to table the request for now but to definitely address it in the module revision.

SIR # 214 deals with validation of the CSU. Discussion included MARLAP and SDWA approaches, detection limit/decision level/MDA, performance-based methods and nondrinking water applications. The committee agreed with requestor's interpretation and that no additional wording was needed. Bob indicated that he would return the response to the Quality Systems Committee.

The committee continued review of Module 6 based on Distributed Document #2 (Collected Comments). Scope discussions included ICP-MS and KPA which were excluded from Module 6 in previous revisions. Because these two instruments/methods are much more prevalent in radiochemistry laboratory testing, they should now be included. There was unanimous consent to remove the exclusion from the Module 6 scope statement and update it as follows:

*The elements of this module apply to techniques used for the purpose of measuring or monitoring radioactivity, or determining compliance with regulations pertaining to radioactivity. The laboratory may choose to comply with corresponding sections of Module 4 in cases where technique-specific QA/QC is not defined by Module 6 (e.g. Mass Spectrometry (ICP-MS, TIMS) or Kinetic Phosphorimetry) or by the reference method (e.g., calibrations, calibration verifications, determinations of detection statistics, or method-specific quality controls). The laboratory must identify in their quality manual and SOPs how and when they are complying with the requirements and elements of both Module 4 and Module 6.*

We began discussing the list of definitions distributed by email. Added terms should be compared / reviewed with the terms and definitions in Module 2. Yield and tracer terms will need discussion either in section 1.3.1 or later in the Module. We were reminded that the standard applies to environmental samples but not to food or radiobioassay. The committee decided to work on the definitions as we proceed through later Module 6 sections. We will attack the definitions as we work through the module adding terms to the terms and definitions section as appropriate.

Section 1.3.2 Exclusions and Exceptions

There was an extended discussion regarding time requirements placed on preparation/ sample batches. The discussion focused largely on gamma spec batch QC. Current QC requirements cause delays in reporting results and significantly increase the rate of QC sample analysis. We may need to differentiate between preparation steps and the chemical separation/ measurement steps to ensure that we maximize batch size and still include appropriate control samples, blanks, duplicates, and matrix spikes. Redefining what a batch, however, may be a difficult sell since it is defined in Module 2 and is uniformly accepted across all the other Modules. Tom volunteered to put together a proposal that carefully walks the fine line between quality and production. The group was asked to provide batching ideas.

**\*\*\*\*\* Group reminder: Complete NELAC committee application\*\*\*\*\***

We will meet next time on October 26, at the same time (2 PM Eastern Time)

The meeting adjourned at 3:52 PM ET.

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## Minutes of Conference Call of the Quality Systems for Radiochemistry Committee

**Date/time:** 8/24/2012 at 2:30 ET

**Participants:** Bob Shannon, Sreenivas Komanduri, Marty Johnson, Dave Fauth, Tom Semkow, Chandra Eschandrasedaran, Carolyn Wong, Keith McCroan, Joe Pardue, Nile Ludtke, Larry Penfold, Terry Romanko

The agenda was distributed by email on 8/21 along with several documents.

1. Draft Module 6 updated per our discussions
2. Radiochemistry Committee Charter
3. PowerPoint about TNI Consensus Standards Process
4. Collected Comments from several committee members for Friday's call.

### Agenda

1. Review and approve minutes
2. Review Charter and discuss the process moving forward as a TNI committee
3. Go through the Powerpoint (quickly)
4. Begin the review of module 6 based on comments received
5. Set up next meeting

Roll call

We talked about how the subcommittee has been elevated to a committee. Members will have to join TNI. We quickly reviewed the Committee Charter. We then went through a PowerPoint on the TNI Consensus Standards Process.

We began discussing Module 6 based on comments collected from the group and distributed in advance of the call.

#### 1.1 Introduction Comments:

- The term "Radiochemical" is favored over "radioanalytical".
- Include reference that general quality systems requirements are specified in module 2 with additions as specified in this module (module 6)
- Need clarifying statement that quality system includes both QA and QC
  - Tom will work on wording of last sentence.

#### 1.2 Scope Comments:

- We had a lengthy discussion on whether ICP-MS and/or KPA should be considered mass/metals measurements.

- Carolyn asked whether we are copping out by excluding ICP-MS which is becoming more and more prevalent in radiochemistry labs.
- Vas supports splitting these techniques off since they are not a radiometric techniques defined in the text. He emphasized that they use different detection statistics and that the rad module does not apply. He proposed that we consider ICP-MS and TIMS in a later revision.
- Tom Semkow expressed opinion not to include ICP-MS and/or KPA at this stage of the Module 6 development, since it would require extensive additions in the following sections as well. Instead, a reference to these methods would be preferred. These methods could be reconsidered at a later time in the future revisions of the draft.
- Bob pointed out that this is the scope statement of the module – and if we really need to get agreement on what should be in the module before we continue on with the module.
- Marty pointed out that rads and metals labs take very different approaches to determining decision limits. Metals chemists are not at all familiar with more rigorous estimations of uncertainty, and do not have experience reporting uncertainty. Even when a non-radiometric technique is used to determine radionuclides, for example to support compliance with NRC, DOE or other regulations, it is being run and interpreted together with radiometric techniques. It is therefore important that the approach to estimating uncertainty and reporting the data be consistent throughout the dataset.
- Bob pointed out that moving these techniques to the metals module may mean that rad labs have to apply for an additional field-of-testing, even though they do their analyses for "rad/nuclear" clients. There are not likely metals labs out there that run the KPA. On the other hand, rad labs that run ICP-MS. Metals chemicals and assessors may be unfamiliar with KPA and its respective analysis protocols, just as radiochemists may not have a good handle on the details of ICP-MS.
- Terry mentioned that the metals department at their lab runs the KPA.
- Bob responded that this is a bit different since Terry's lab maintains both metals and radiochemistry capabilities. He also pointed out that the requirements we are concerned with (calibration, cal-verification, and QA/QC) are defined in most methods. We could also reference module 4 requirements from Module 6. We would have to figure out how to discriminate between ICP-MS for metals and ICP-MS for rad.
- In the end, there was weak agreement, and some disagreement, that these techniques should be described in Module 6 and that we could point to requirements in Module 4. Nile made a suggestion of language that addresses that these techniques may be included in Module 6 when used for radiochemical testing, but that Module 4 sections can be included by reference.
- There was consensus, with Tom's proposal that "...some form of..." be removed from second sentence.
  - i.e., Procedures for radiochemical testing may involve chemical separation followed by ...

### 1.3 Terms and Definitions Comments

- There was consensus that it is much easier to word and make understood the whole module if this section includes and defines most concepts so readers can refer to this section to get the definition and then understand it consistent use in module 6.
- Group will send terms and definitions to the entire group ASAP to facilitate discussion before the next meeting.

[After the meeting, Bob sent out an email suggesting that we look at Module 1 (which contains some definitions). If it is missing some, he suggested considering MARLAP as a starting place for definitions. If so, people can just send him the terms and he will compile a list of terms for the next meeting. If people think definitions need tweaking, send them to Bob and he will add them to the list.]

We will meet next time on September 24, at the same time same time (2 PM Eastern Time)

The meeting adjourned at 3:30 PM ET.

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### **Notes/Minutes for TNI Radiochemistry Module 6 Subcommittee**

**Date:** July 27, 2012 at 14:00 ET

**Participants:** Sreenivas Komanduri, Marty Johnson, Dave Fauth, Tom Semkow, Carolyn Wong, Keith McCroan, Joe Pardue, Todd Hardt, Nile Ludtke, Larry Penfold, Terry Romanko, and Bob Shannon.

#### **Agenda**

NEXT MEETING: It was agreed that the next meeting would continue to be held the fourth Friday, August 24 at 1400 ET. Dave Fauth was the only participant who would not be able to participate.

No one on the call had any issues or additions about the previous meeting's notes.

REVIEW OF Module 6: Bob Shannon briefly reiterated the subcommittee's mission and indicated that the focus the discussion of the day should be on the red line changes. Our review should identify those changes that will create major issues if implemented. Minor clarifications and wish list items will be discussed later by this subcommittee.

Group discussion revealed that there had already been two votes on the changes and that the committee was trying to address concerns with voting members. One member of our subcommittee indicated that his concerns had not been addressed.

#### **SUMMARY OF REVIEW COMMENTS:**

**Section 1.4 Selection of Methods** Prior contents deleted with referral to Volume 1 Module 2 sections 5.4.2, 5.4.3 and 5.4.4 that are excerpts from ISO 17025.

Comments were that the change made it less user friendly to use but it was done so there was agreement with ISO 17025. Bob said he would ask why the change was made while at NEMC.

**Group opinion that change was acceptable.**

**Section 1.5.1 Validation of Methods** Items a and b were deleted. Item c re-written as a with two additional items added.

Comments were that reference methods are validated differently. The topic of uncertainty needs to be addressed in this section.

**Group opinion that change was acceptable but uncertainty should be included in next revision (Bob to get more information while at NEMC).**

**Section 1.5.2 Detectable Activity** Re-written.

Comments were that MDC should also be discussed in this section but that should be addressed in a later revision.

**Group opinion that this section should be titled Detection Capability.**

**Section 1.5.2.1 Minimum Detectable Activity (MDA)** Changes made to items a) and d).

Comments were that the definition for MDA should be generalized and not be restrictive. SWDA standard lists 3 ways to calculate detection limits. The definition for MDA in part d) has been butchered and is meaningless. Assessors are asking for MDC (Bq/kg).

**Group opinion that this section changes should be eliminated, i.e., revert back to previous version.**

**Section 1.5.5 Evaluation of Selectivity** No redline changes

Comment that Gross alpha and gross beta are nonselective methods.

**Group opinion that this section needs more detail (next revision).**

**Section 1.6 Demonstration of Capability**

**Section 1.6.1 General** Rewrite places emphasis on analyst

Comments were generally favorable with the focus on the analyst.

**Group opinion that change was acceptable.**

**Section 1.6.2.2** No redline changes

Comment that section should be revised.

**Group opinion that this section needs more detail (next revision).**

**Section 1.7 Technical Requirements**

**Section 1.7.3 c) Background Measurements** Change from requiring weekly to quarterly for gas-proportional counters background measurements

Comments were that this change was made to conform with "old" ANSI standard. Quarterly is considered too long between consecutive background measurements and could cause a laboratory to lose a lot of data although standard does indicate that the background measurement should not take the place of a contamination check. This standard should not jerk laboratories around with frequency changes.

**Group opinion that the frequency remain at "weekly" to minimize changes that laboratories will need to implement until a more complete revision of the section can be prepared (next revision).**

**PATH FORWARD**

Bob Shannon will cover group opinions with the QC committee chair while at NEMC. For the next meeting, the committee should review the first part of the 2011 Module 6 through section 1.5. Identify sections that need attention (corrections, additions, deletions), provide suggestions for updating the sections, and send these to Bob (BobShannon@boreal.org) by 8/17. He will summarize these and distribute to the group. These will become the basis for the discussion on the next teleconference.

Meeting was concluded at 1530 ET.

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**Notes/Minutes for TNI Radiochemistry Module 6 Subcommittee**

**Date:** 6/26/2012 at 15:00 ET

**Participants:** Bob Shannon, Sreenivas Komanduri, Marty Johnson, Dave Fauth, Tom Semkow, Carolyn Wong, Joe Pardue, Keith McCroan, Todd Hardt, Nile Ludtke, Terry Romanko

**Agenda**

A. Each member introduced themselves to the group.

B. Bob Shannon presented the subcommittee's mission. We will review Module 6 of the 2011 TNI Standard. While the overall format of the standard presents limitations to the scope, we should work to identify and update items to be appropriate for radiochemical laboratories doing environmental analysis as part of NELAC. The standard is based, among others, on ISO 17025, so there should be ways to address most issues within the framework of the module. The TNI standard is first and foremost a quality systems standard. Thus we will need to be careful to not be prescriptive, and need to keep in mind that especially most radiochemistry labs rely heavily on performance-based methods, but also perform analysis under programs such as SDWA/CWA. In other words, the final standard should focus generally on requirements for analysis types, as opposed to individual methods.

C. Members shared general thoughts about the TNI standard and our mission.

Joe Pardue – Supports keeping the group small, make incremental changes to the standard – much work is needed

Tom Semkow – Especially the sections on calibration and instrument check frequencies and evaluation, MDAs, MDCs and SDWA DL, and preparation and analytical batches, need work

Vas Komanduri – Radiochemistry methods dating back to the 1980s are not strong on QA sections – need to beef up requirements to support this weakness; Also should consider availability of PT samples specific to radchem, their frequency, and associated criteria. We discussed that this is outside the scope of Module 6. Joe Pardue, however, is on the PT committee and said that he would be willing to take our comments and suggestions to them. Bob Shannon will check with the QC committee chair. Perhaps we can reserve time after we finish going through our module to look at PTs.

RTS – Need to consider addressing imprecise language that creates ambiguity for labs and auditors

#### **D. Moving forward**

Bob asked if people would be attending NEMC (August 6-10 in WA DC) since this could be a possibility to meet, assuming enough people attended. Only two people are going, so for now, that thought was tabled. RRMCM, later in the year, might also offer a similar opportunity. Here is a link to the website: <http://nemc.us/>

We decided to continue meeting Friday afternoons (4<sup>th</sup> Friday of each month) one hour earlier than this week. The next meeting will be on Friday, July 27, at 2 PM ET (1 PM CT; 12 PM MT; 11 PM PT)

Dave Fauth volunteered to be the scribe and take notes for the record.

Communication with the committee – there were some problems with delivery of emails. Bob will request read receipts – please respond so that he can see who is NOT getting emails.

For next time, committee members should review the 2011 Module 6 through section 1.5. Identify sections that need attention (corrections, additions, deletions), provide suggestions for updating the sections, and send these to Bob ([BobShannon@boreal.org](mailto:BobShannon@boreal.org)) by 7/20. He will summarize these and distribute to the group. These will become the basis for the discussion on the next teleconference.

#### **E. Additional Items Discussed:**

Tom Semkow asked what changes were made to 2009 in the 2011. There were a number of changes made, apparently not all for the better. Bob will get a redline copy of the revised (2011) version of Module 6 and will distribute to the group before the next meeting.

Vas Komanduri asked about whether Rn labs, and the sections addressing lab measurements of radon where within scope. Bob will check on this before the next meeting.

Carolyn Wong asked about getting a Word version of Module 6. Bob will look at getting a copy, will add line numbers and create a PDF from which we will work, but will also distribute the Word version of the document to the committee – before the next meeting. .

The teleconference ended at 15:50 ET

The next conference call will be Friday, July 27, at 2 PM ET (1 PM CT; 12 PM MT; 11 PM PT)

### **Attachment 3 - Minutes from the September 28, 2012 Meeting – As considered and adopted on the October 26, 2012 Committee Conference Call**

**Date/time:** 9/28/2012 at 2:00 ET

**Participants:** Bob Shannon, Sreenivas Komanduri, Marty Johnson, Dave Fauth, Tom Semkow, Carolyn Wong, Todd Hardt, Nile Ludtke, Richard Sheibley, Terry Romanko,

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7. If Ken Jackson from TNI can be on the call, we will discuss organizational matters.
8. Continue review of Module Six
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**\*\*\*\*\* Group reminder: Complete NELAC committee application\*\*\*\*\***

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The meeting adjourned at 3:52 PM ET.