

Quality Management System Expert Committee (QMS)
Meeting Summary
San Antonio, TX

January 19, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 8am Central in San Antonio, TX on January 19, 2022, Attendance is recorded in Attachment A – there were 9 voting members present: Nick Slawson, Kathi Gumper, Michael Demarais, Nicole Cairns, Ashley Larssen, Tony Francis, Amy Schraeder, Stephanie Atkins and Debbie Bond.

Debbie shared the agenda in the meeting presentation (Attachment B).

2. Workgroup Reports

Definitions

Paul Junio presented the work being done by this committee. He shared different definitions that the Committee is working on – see Attachment B for slides.

Matrix Duplicate - This definition becomes a problem with Air. There aren't matrix duplicates, so you can't require it. This comment will be submitted in writing to the Chemistry Expert Committee and Quality Management Systems.

Customer - The customer is the person you are in contract with.

Comments on the slides should be sent to Debbie. She will share them with Paul and the Workgroup.

Language Workgroup

Nicole Cairns presented the work being done by this Workgroup. See slides in Attachment B for details discussed.

The Workgroup completed their first task and will share that today. The second has been started and the last 3 have not been started.

Section 4.2.8.5 - SOPs

They looked at the whole section instead of one clause. She shared current language, proposed language and the justification. This is summarized in the slide.

Proposed language: a) - Add the word “collectively” in front of sentence.

Proposed language: b) - Comment made that they would like to see redundant language remain.

It was commented that removing the redundancies means the information is now in other parts of the Standard. Is there a need to keep some of the redundancies in order to keep all the information in one place?

Notice that the language now makes it clear what is needed under the test method SOPs and did not get specific with general/administrative procedures.

Asked if required items can have a specific standard reference.

It was commented that the information being presented today may change numbers. The numbers today are based on the 2016 Standard and when placed in the new Standard the numbers will change.

3. Continued Review of 17025 Crosswalk

Debbie brought up the Crosswalk table being used to determine changes to the new Standard.

The Committee started work again in Section 5.6.1.

5.6.2.1.1 - Note 1 - All voting members were in agreement that the note is not needed.

Nicole commented that the committee thought 5.6.2.1 was relevant to calibration labs so not applicable to testing labs. Kathi noted that 5.6.2.2 refers back to some of these.

The info in 5.6.2.1 is relevant because calibration labs contracted by the lab need to do these things.

Note - 5.6.3.4 - Change from deleted to equivalent.

Section 5.7

There are some conflicts in the comments. The language should remain because some labs do do sampling.

Leave the ISO language as it is. Recommend keeping the ISO/IEC 17025 language as is.

Suggest that it needs to be clear what sampling happens in the lab (sub sampling) and the sampling done in the field with the lab.

Section 5.8

Leave as is.

Section 5.9

Leave as is.

Section 5.10

Suggestion to add more language to 7.8.1.3 in new ISO Standard. It was commented that this is one of the most confusing clauses in the new Standard. They are seeing it be cited by assessors as a catch all.

BREAK

Debbie reminded everyone that this will all go through a second review.

She will skip the sections on Technical Manager. She recommended that people attend the meeting tomorrow morning where Technical Expert will be discussed.

Someone questioned whether equipment used rarely - only to check another thermometer - does it really need to be checked annually? Maybe leave that up to the lab? The Committee considers it a reference and it shouldn't require the same calibration frequency. This is currently in Section 5.6.1.

A number of people commented that it really needs to be clear how often the reference equipment needs to be verified.

ISO language says you need to establish a calibration program. In use thermometers need to be checked more frequently. Reference thermometers need to be checked less frequently because they are used less frequently.

This is another one of those crossroads - do we let labs determine their own frequencies or do we continue to give them minimums or tell them what to do. Kathi reminded people that DW has some "requirements" that we may consider leaving in.

Comments are that we probably want to do a middle ground. This is an opportunity to change the language.

Nicole agrees, but would like to set some minimums. Make it clear between working and reference standards. Need to be sure weights are included in this text.

Iлона suggested starting to merge the 2005 language we want to keep into this DRAFT Standard before we really start trying to finalize language in this DRAFT Standard.

Section 8.3.2 :

Add - The end of documents shall be clearly identified. This was in the 2005 language. Is it still needed?

It was commented that we should clarify when changes to documents have to be approved? Do editorial changes have to be approved. It was commented that this is over regulating. Maybe just state that you need a procedure for handling documents and the lab can define this.

Comment to just make it clear.

Remove requirement for making end of page clear. This was updated in the crosswalk document. 2005 language should be dropped.

Ended with discussion of no master list of documents required.

4. SIR 422 - Dec 26, 2021

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.6.4.2
Describe the problem: This section of the Standard specifies, "Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory." Question: What does the Standard mean by "technical operations of the laboratory"? Would a 1:1 HCl dropper used to acidify a VOC sample during sample collection require the documentation and labeling of paragraphs b) and/or d)? Do reagents that are used at collection fall under the definition of "technical operations of the laboratory"?	
Committee Comment: Response: If the laboratory provides or uses the reagents, they would be part of the "technical operations of the laboratory" and would therefore require documented procedures as described in section 5.6.4.2. If the reagents are provided by the client, they would not fall under the "technical operations of the laboratory."	

A motion was made by Kathi to approve the response above. The motion was second by Nicole and unanimously approved. Debbie will send this on to Lynn and LASEC.

5. New Business

No new business.

6. Next Meeting and Close


The next meeting will be February 14, 2022 by teleconference/Webex at 1pm Eastern.

Debbie adjourned the meeting at 11:42am Central.

Attachment A


Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) Present	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumpper (Vice-Chair) Present	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns Present	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais Present	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis Present	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Lizbeth Garcia Absent	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsaha.state.or.us
Stephanie Atkins Present	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson Present	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen Absent	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak Absent	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
William Ray Absent	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross Absent	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Amy Schreader Present	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard Absent	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ashley Larssen Present	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) Present	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org




Quality Management Systems Expert Committee Volume 1 Module 2

Winter Conference Meeting
1/19/2022




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Quality Management Systems Expert Committee

Debbie Bond
Chair
dbond@southernco.com

Kathryn Gumper
Vice-chair



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Quality Management System Committee

Member	Organization	Representation
Nicole Cairns	NYSDOH	Lab
Michael Desmarais	SVL Analytical	Lab
Tony Francis	SAW Environmental	Other
Lizbeth Garcia*	Oregon Dept of Env Quality	AB
Stephanie Atkins	Pace Analytical	Lab
Nicholas Slawson	AZLA	AB
Earl Hansen	Retired	Other
Jenna Majchrzak	NJ DEP	AB
William Ray	William Ray Consulting	Other
Amber Ross*	PA DEP/Bureau of Laboratories	AB
Amy Schreader	UC Laboratory	Lab
Alyssa Wingard	NAVSEA LQAO	Other
Ashley Larsson	KC Water	Lab




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Agenda

- Approve December minutes
- Update Action List
- Recap since summer meeting
 - Update from Definitions Workgroup
 - Update from Language Workgroup
- Crosswalk ISO17025:2005 vs. 2017 missing items
- Draft Standard edits
- New business (SIR 422)




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(Open December Minutes Word Doc)

REVIEW DECEMBER MINUTES & UPDATE ACTION LIST




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Quality Management Systems Expert Committee

Recap

- ISO 17025:2005 vs 2017 Crosswalk
- SIRS
- Workgroup Updates




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ISO/IEC 17025 Crosswalk Workgroup

- Workgroup members
 - Debbie Bond (Chair), Alabama Power General Test Lab (Lab)
 - Kathryn Gumpfer, ChemVal Consulting (Other)
 - Paul Junio, Northern Lake Service Lab (Lab)
 - Ashley Larssen, KC Water (Lab)
 - Amy Schreader, UC Laboratory (Lab)
 - Nicole Cairns, NY-DOH (Lab)
 - Tony Francis, SAW Environmental (Other)
 - Lisa Parks, Jackson Family Wines (Lab)
 - Tina Buttermore, Pace Analytical (Lab)
 - Earl Hansen, Retired (Other)
 - Michael Desmarais, SVL Analytical (Lab)




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ISO/IEC 17025:2005 v 2017 Crosswalk

- March to November 2021
- Found ~60 sections where 2017 requirements did not cover 2005 requirements
- Found ~70 sections in 2005 that are not in 2017 revision
- WG reviewed missing/different requirements to evaluate to keep or not in DRAFT Standard
- In process of presenting to the full committee



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SIRs


- Published SIRs
 - SIR 378 (reference thermometer calibration frequency)
 - SIR 392 (calibration status of analytical equipment)
 - SIR 401 (microliter brand name vs. measurement)
- We are continuing to work on SIR 412 regarding unique labeling of containers of the same preparation.

Disclaimer

- The following SIR is not complete. Any response described must be approved by LASEC and AC before it may be posted. The response may change.




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SIR 416

- 416 on section 5.6.4.2.c
 - The standard as written states, "Records shall be maintained on standard, reference material, and reagent preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials."

Does the laboratory need to have a single document that includes each of these items or can the laboratory's record keeping system allow multiple records/documents (including electronic) that contain or reference the required items? Or more simply, can the Standard be interpreted to mean that "reference to" can be applied to the string/list of items, such as the record may include a "reference to" the method of preparation, "reference to" the date of preparation, "reference to" the expiration date and "reference to" preparer's initials?




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Quality Management Systems Expert Committee

Definitions Workgroup Report




January 19, 2022

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Definitions Workgroup

- Workgroup members
 - Paul Junio (Chair), Northern Lake Service Lab (Lab)
 - Lizbeth Garcia, Oregon Dept of Environmental Quality (AB)
 - Jenna Majchrzak, NJ Dept of Environmental Protection (AB)
 - Amy Schreader, UC Laboratory (Lab)
- Mission
 - To evaluate requests for definitions of specific terms of Volume 1, Module 2 of the 2016 TNI Standard. Where a definition is needed, develop definitions that align with the Standard and, where appropriate with other TNI documents, and to present to the QMS Expert Committee for consideration.




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Definitions Workgroup

Annual – A period of 12 months, not to exceed 13 months.

Quarterly – A period of 3 months, not to exceed 4 months.




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Definitions Workgroup

Note that a requirement that something be done every 12 months is NOT the same as one that is done annually. Annually would allow for not exceeding 13 months. How any one Module describes the time could matter.

We did NOT address 'Monthly', as we didn't feel we could come to an adequate conclusion.




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Definitions Workgroup

Matrix Duplicate: A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision. [Module 2]

Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. Matrix duplicates are performed on replicate aliquots of actual samples. [Module 4]




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Definitions Workgroup

Duplicates: randomly select routine samples to be analyzed twice. Process duplicate sample independently through the entire sample preparation and analysis. [Standard Methods]

Laboratory Duplicate: Two sample aliquots, taken in the laboratory from a single sample bottle, and analyzed separately with identical procedures. [EPA 300 Series]




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Definitions Workgroup

Duplicate – repeat of the same analytical measurement multiple times. Depending upon method and program requirements may be multiple preparations or multiple measurements of the same preparation.

Do we really need that additional definition?




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Definitions Workgroup

Support Equipment – Equipment used to determine results that are not reported as a final test result, but are used in support of other results

Customer – the end data user. [this implies that a regulatory authority may be the customer rather than a person submitting samples – maybe 'the party that requested data from the laboratory']




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Definitions Workgroup

Others to consider:

- Method validation
- Verification
- Procedure
- Policy



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Quality Management Systems Expert Committee

Language Update Workgroup Report

January 19, 2022




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Language Update Workgroup

- Workgroup members
 - Nicole Cairns (Chair), NY-DOH (Lab)
 - John Gumpfer, ChemVal Consulting (Other)
 - Meera Neb, Technical Testing International (Lab)
 - Lisa Parks, Jackson Family Wines (Lab)
 - Nick Slawson, A2LA (AB)
- Mission
 - To update language for specific clauses of Volume 1, Module 2 of the 2016 TNI Standard where clarification or changes are needed and to present the updated language to the QMS Expert Committee for consideration.




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2016 V1M2 Assignments

- Clause 4.2.8.5 – **Completed**
 - Clarify differences between analytical/technical and support/QMS documents
 - Clarify listed items are not a required outline of sections for procedures
- Clause 5.8.5 – **In Process**
 - Evaluate use of word “unique” in sample identification
- Clause 8.8.2 d) – **ISO/IEC 17025:2017** clause
 - Clarify what is meant by “undue delay”
- Clause 4.13.3 b)
 - Review record retention requirement last “entry” versus last “use”
- Clause 5.6.4.2 d) – from SIR 412
 - Clarification of unique ID for standards, reference materials and reagents



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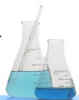
2016 V1M2 Clause 4.2.8.5

- Current Language


4.2.8.5 Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all methods.
- Proposed Language

4.2.8.5 The laboratory shall maintain documents that accurately reflect all current laboratory activities.

 - a) These documents shall provide instruction for implementing management system requirements and test method requirements.
- Justification
 - Replaced “SOP” with documents to align with **ISO/IEC 17025:2017** language
 - Removed extraneous examples that do not add to the standard

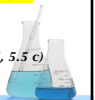


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2016 V1M2 Clause 4.2.8.5

- Current Language
 - a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents with adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result.
- Proposed Language
 - b) These documents may be from external sources or internally prepared. For example, they may be equipment manuals provided by the manufacturer, published reference methods, or internally written procedures. **External documents that contain sufficient information to perform the activity do not need to be supplemented or rewritten as internal procedures.**
- Justification
 - Underlined text was removed as it is redundant with **ISO/IEC 17025:2017, 5.5 c)**
 - Highlighted text pulled up from clause d).




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2016 V1M2 Clause 4.2.8.5

- o Current Language
 - b) The relevant SOPs shall be readily accessible to all personnel.
- o Proposed Language
 - None – clause deleted
- o Justification
 - Removed as it is redundant with *ISO/IEC 17025:2017, 7.2.1.2*




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2016 V1M2 Clause 4.2.8.5

- o Current Language
 - c) Each SOP shall clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority.
- o Proposed Language
 - None – clause deleted
- o Justification
 - Removed as it is redundant with the intent of *ISO/IEC 17025:2017, 8.3.2*




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2016 V1M2 Clause 4.2.8.5

- o Current Language
 - d) Documents that contain sufficient information to perform tests, do not need to be supplemented or rewritten as internal procedures if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option, shall be documented and included in the laboratory's records.
- o Proposed Language
 - None
 - + Requirements in first sentence moved to end of new 4.2.8.5 b)
 - + Requirements in second sentence moved to new 4.2.8.6 a) and b)
- o Justification
 - Requirements were moved to align topics within clauses and provide clarity

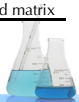


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2016 V1M2 Clause 4.2.8.5

- o Current Language
 - e) The laboratory shall have and maintain an SOP for each accredited analyte or method.
- o Proposed Language
 - 4.2.8.6 The laboratory's test method documents shall include instructions for all fields of accreditation.
- o Justification
 - Made a new section as this section is just specific to test method documents.
 - Changed to field of accreditation to incorporate analyte, method, and matrix to align with Scopes of Accreditation




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2016 V1M2 Clause 4.2.8.5

- o Current Language
 - f) ~~The SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each method shall include or reference the following topics where applicable:~~
- o New Language
 - 4.2.8.6 a) In cases where modifications to published reference methods have been made by the laboratory, these modifications shall be clearly identified and described in the test method instructions.
 - b) In cases where the published reference method provides options, is ambiguous, or provides insufficient detail, the choices and/or clarifications made by the laboratory shall be clearly identified and described in the test method instructions.
 - c) These instructions shall include or reference the following topics where applicable:
- o Justification
 - First sentence deleted as it is now covered in 4.2.8.5 b).
 - Separated remainder of requirements into two separate sections for added clarity.



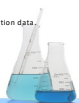
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2016 V1M2 Clause 4.2.8.5

- o Current Language
 - f) ...Each method shall include or reference the following topics where applicable:

<ul style="list-style-type: none"> ➢ i. identification of the method; ➢ ii. applicable matrix or matrices; ➢ iii. limits of detection and quantitation; ➢ iv. scope and application, including analytes to be analyzed; ➢ v. summary of the method; ➢ vi. definitions; ➢ vii. interferences; ➢ viii. safety; ➢ ix. equipment and supplies; ➢ x. reagents and standards; ➢ xi. sample collection, preservation, shipment and storage; ➢ xii. quality control; 	<ul style="list-style-type: none"> ➢ xiii. calibration and standardization; ➢ xiv. procedure; ➢ xv. data analysis and calculations; ➢ xvi. method performance; ➢ xvii. pollution prevention; ➢ xviii. data assessment and acceptance criteria for QC measures; ➢ xix. corrective actions for out-of-control data; ➢ xx. contingencies for handling out-of-control or unacceptable data; ➢ xxi. waste management; ➢ xxii. references; and ➢ xxiii. any tables, diagrams, flowcharts and validation data.
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2016 V1M2 Clause 4.2.8.5

Proposed Language


f) ...These instructions shall include or reference the following topics where applicable:

i) These topics must be included in the instructions:

- identification of the method,
- applicable matrix or matrices,
- scope and application, including analytes to be analyzed,
- summary of the method,
- interferences,
- safety measures for hazards specific to the test method, beyond general safety measures covered below,
- equipment and supplies,
- reagents and standards,
- sample collection, preservation, shipment and storage,
- complete list of quality controls to be analyzed and preparation instructions for those quality controls,
- type of calibration to be analyzed and calibration instructions,
- procedure,
- data analysis and calculations, and
- references.



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2016 V1M2 Clause 4.2.8.5


ii) These topics must be addressed but may be included by reference to other documents or records:

- definitions,
- limits of detection and quantitation,
- calibration evaluation and acceptance criteria,
- data assessment and acceptance criteria for quality controls,
- actions for handling out-of-control or unacceptable data,
- general laboratory safety, and
- pollution prevention and waste management.


iii) These topics are optional:

- additional information on method performance and
- any tables, diagrams, flowcharts and validation data.

Note: The bulleted lists here are the topics to be covered and are not intended to provide any document formatting requirements.




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2016 V1M2 Clause 4.2.8.5

Justification

- Not all topics need to be laid out in the procedure so broke topics into 3 sections
 - + Must be included
 - + Must be addressed but can be referenced to other documents
 - + Optional
- Added some clarity to the intent of some topics (underlined text in previous slides)
 - + Broke out safety into test method specific safety and general laboratory safety
 - + Added clarity to quality controls
 - + Added clarity to calibration, broke into two categories: type and instructions & evaluation and acceptance criteria
 - + Removed outdated "standardization" term as it applies to calibration
 - + Combined corrective actions and contingencies for out-of-control data into one topic
- Note added to clarify that these are not section headings




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(Open ISO17025 Crosswalk 20211116.docx, begin at 5.6)

CONTINUE REVIEW OF ISO 17025:2005 V 2017 CROSSWALK




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(Open ELV1-M2 v202-210909.doc)

DRAFT STANDARD EDITS




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(Open SIR 422 to QMS 12262021.docx)

NEW BUSINESS



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