



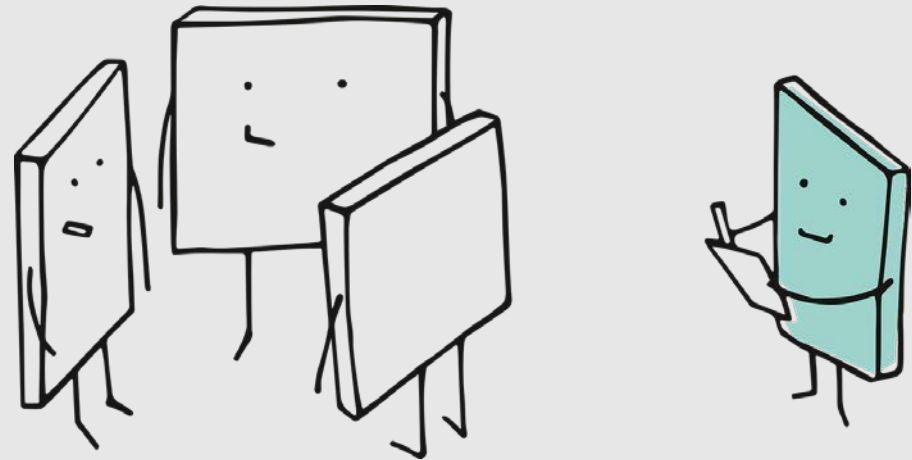
# VENDOR AUDIT RELIEF OPTIONS

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# Background

- Vendor audits are to be completed on a 36-month frequency
- Most utilities have adopted an NRC-approved SER that allows for a 25% (i.e. 9 months) grace period to complete an audit beyond the 36-month period
- Most vendor audits are coordinated through NUPIC and adhere to NUPIC and EPRI guidance, utilizing a performance-based approach
  - Performance-based auditing guidance requires direct observation at the vendor facility
  - Common interpretation of Appendix B Criterion VII is that supplier audits must be conducted at the vendor facility



## Current Issue

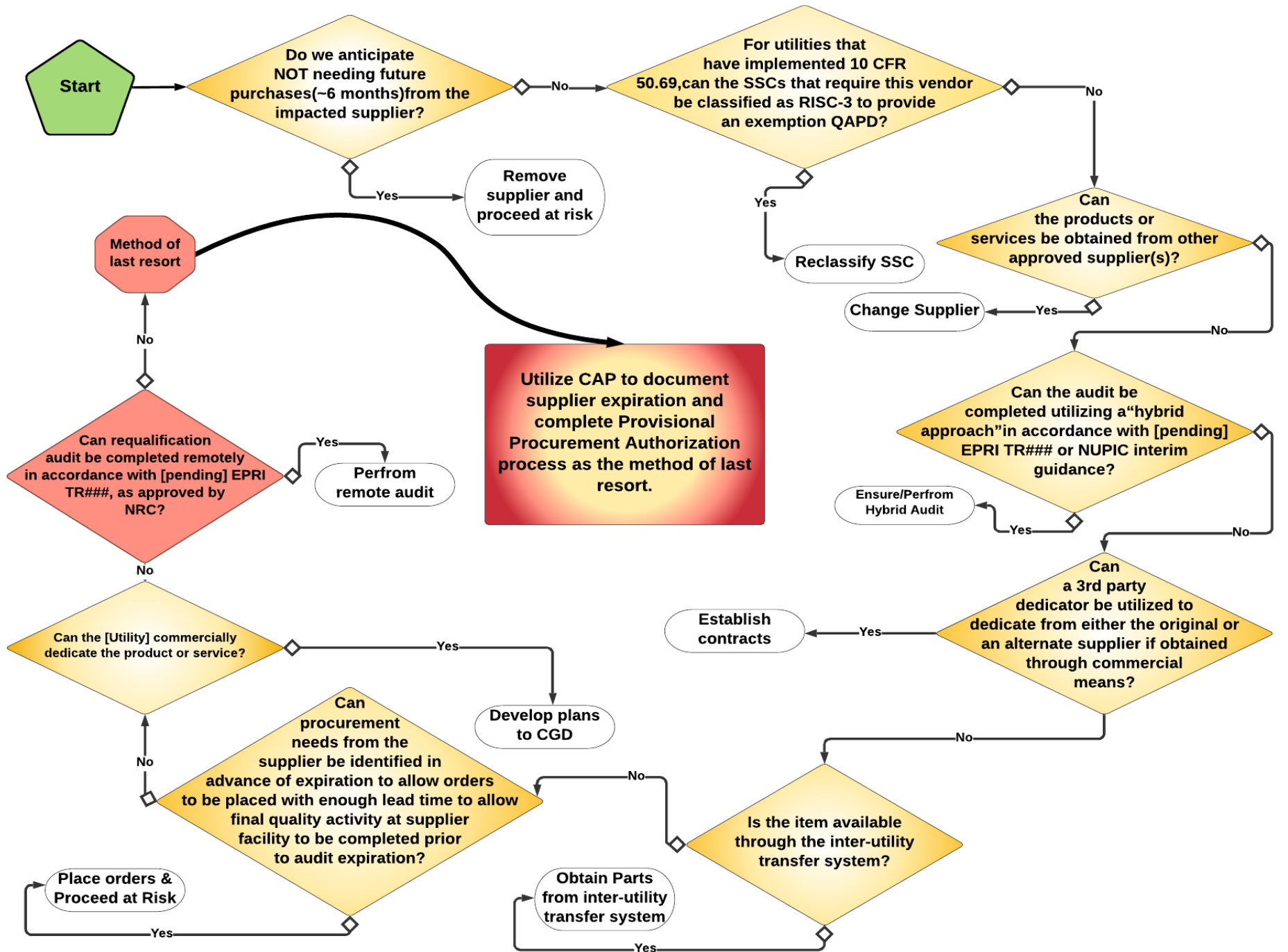
- COVID-19 related travel restrictions, both domestic and international, are precluding the ability of station QA personnel from conducting audits of vendors required by Criteria VII and XVIII of Appendix B and utility QA plans.
  - Personnel travel is challenged across state and international lines
  - Some suppliers are restricting access to their facility
- One international supplier's 9-mo grace period will expire Jan 2021
- Additional international and domestic suppliers' 9-mo grace period will expire Feb 2021

**TRAVEL  
RESTRICTIONS**

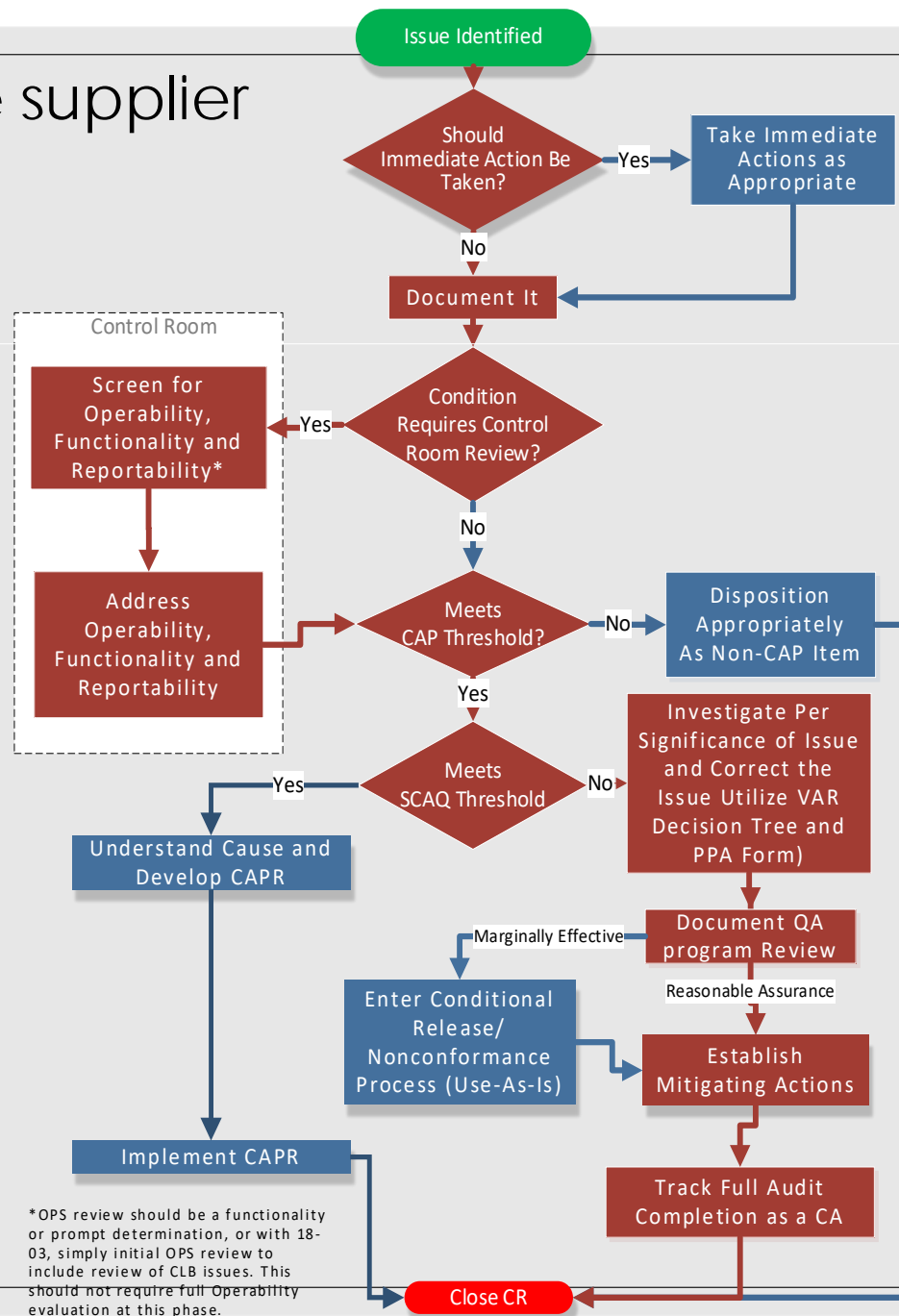
# What is being done to mitigate these challenges?

	Technique	Document	Timeline	Approval	QAPD Change	Change Management	Impact
NUPIC	Hybrid - Allows ATL to determine on-site presence with NUPIC Steering Committee concurrence	NUPIC Guidance document	Approved September 2020	NUPIC	No	Requires advance planning with ATL, vendor & impacted utilities	Covers gap to EPRI TR approval.
EPRI	Remote - Expands on hybrid approach and provides roadmap for performing remote audits.	EPRI Technical Report	Late 4Q20	EPRI, will likely require station submittal to NRC to allow use of fully remote provisions.	Expansion of hybrid approach unlikely to require QAPD change, while allowing fully remote will require NRC approval.	Requires advance planning with ATL, vendor & impacted utilities. Procedure changes and technology training required.	Will remedy issue.
VARs	Decision Tree - Provides roadmap to assist station management during 'gap' when grace expires and EPRI TR is available.	Decision tree and change management materials	October 2020	NQML SC NUPIC SC	No	Will require training to station leadership team, procurement, station QA and engineering.	Covers gap to EPRI TR approval
VARs	PPA - Describes methodology to use CAP to document evaluation for approval of the supplier, part or service as the method of last resort.	Procedure and associated 50.54(a)	4Q20	NQML SC NUPIC SC	Possible, but may exist as temporary procedure or bridging document.	Will require substantial training and outreach to station leadership team, procurement, station QA and CAP.	Covers gap to EPRI TR approval

# Decision Tree



# Use of CAP to evaluate supplier



\* OPS review should be a functionality or prompt determination, or with 18-03, simply initial OPS review to include review of CLB issues. This should not require full Operability evaluation at this phase.

## Basis for Provisional Procurement Authorization

- Continued use of suppliers that have exceeded the maximum allowed audit or survey time due to extenuating circumstances is allowed if the following conditions are met:
  - a. A documented evaluation\* must be performed to summarize why the audit or survey could not be performed prior to the end of the **25% (9-month) grace period, and to provide the basis for utilizing the supplier after the grace period has expired**. While implementing procedures must describe elements to be included in the documented evaluation, the following items should be considered as applicable:
    - For 10 CFR 50, Appendix B suppliers, verification that the supplier's quality assurance program is still committed to meeting the requirements of 10 CFR 50, Appendix B.
    - For commercial suppliers who are approved based on commercial grade survey, verification the supplier has maintained adequate documented programmatic controls in place for the activities affecting the critical characteristics of the item/services being procured.
    - Evaluation of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and any open findings since the previous triennial audits describing impact on the items/services being procured from that supplier.
    - Review of procurement history since last triennial audit/survey including receipt inspection results to identify any potential issues. The results of the performance history must be included in the evaluation.
    - The degree of standardization of the items being procured. For instance, suppliers of catalog items which are used across multiple industry with widely accepted good performance histories would be considered good candidates **to allow extended use of a supplier after the 25% (9-month) grace period has been exceeded**.

\*If a licensee's initial 25% grace provisions require this evaluation be completed, then the evaluation must be updated to determine if any new information exists that could change the outcome of that evaluation for the purpose of supporting a Provisional Procurement Authorization.

Note: *blue font is used on this and the following page to distinguish differences from similar conditions contained in ML20216A681.*

## Basis for Provisional Procurement Authorization cont'd

b. If concerns are identified based on the above evaluation, the following mitigating actions may be considered:

- Enhanced receiving inspections beyond visual inspections and quality checks.
  - Based on safety-significance and complexity of item, consider use of remote source verification as approved in ML20181A445.
- Identification of any additional requirements/restrictions to be placed on the supplier.

c. For audits/surveys performed **after** the 25% grace period, the audit/survey shall include a review of activities performed by the supplier since the 36-month audit/survey expiration date.



## Example Evaluation within CAP

- Refer to handout example
- Evaluation has two parts
  - Part A focuses on Supplier QA program
    - Note: The use of red font in Part A represents information selected to force the example to demonstrate the additional evaluations in Part B.
  - Part B focuses on technical and quality characteristics of specific item, if needed

## Summary

- Multiple efforts in progress to maintain nuclear supply chain
- All options to complete audits or secure procurement alternatives would be explored prior to allowing a supplier's audit to expire after grace is exhausted
- Corrective Action Program option is reserved until all other means are explored
  - Provides formal means of tracking audit completion
  - Visibility with station leadership
  - Utilizes mitigating actions already approved by NRC

## Proposed approach for implementation

- Prior NRC approval not needed for decision tree or use of CAP
  - Procedure changes governing treatment of suppliers on Qualified Supplier List below threshold of QATR program description
  - Supplier status would be treated as “conditional” with appropriate conditions and mitigating actions specified
  - Further evaluation of specific part or service fits within nonconformance or conditional release process

## Preliminary 50.54(a) screening of use of CAP

- Change being evaluated:
  - Example Quality Assurance Topical Report (QATR) reviewed – no changes to QATR
  - Example procedures reviewed – change procedure provision requiring supplier status be changed to “inactive” on the Qualified Supplier List (QSL) if the audit has not been completed by the audit expiration date including 25% grace, to a status of “conditional” if a documented evaluation supports a provisional procurement authorization

Question	Disposition
Exclusion Questions of 50.54(a)(3)	Not excluded – requires further review
Conflict with Part 50 App B?	No Criterion VII – continue to assess effectiveness of control of quality by contractors Criterion XVIII – audits shall be performed in accordance with written procedures Criterion XVI – measures shall be established to assure that conditions adverse to quality such as nonconformances are promptly identified and corrected

## Preliminary 50.54(a) screening of use of CAP, cont'd

Question	Disposition
Conflict with QATR commitment?	No; Level of detail that requires removing overdue vendors from QSL is in procedures and not in QATR. Regulatory guidance does not specify actions for treatment of supplier if audit expires.
Eliminate a function, control or activity from QATR?	No functions, controls or activities eliminated. NOS still evaluates effectiveness of vendor QA program in PPA and will perform audit when conditions allow.
Reduce size or scope of organization in QATR?	Scope remains static
Any other reason change would reduce QA program commitments?	Supplier would not be reapproved on QSL until audit is completed. Provisional or conditional use of the supplier will be documented in CAP and evaluated.
<b>Conclusion</b>	<b>Prior NRC approval on use of CAP as method of last resort is not needed</b>

## Closing

- NRC feedback
- Identify any follow-up actions

## Acronyms used

ATL	Audit Team Lead	PPA	Provisional Procurement Authorization
CAP	Corrective Action Program	QA	Quality Assurance
CAPR	Corrective Action to Prevent Recurrence	QAPD	Quality Assurance Program Description
CGD	Commercial Grade Dedication	QATR	Quality Assurance Topical Report
EPRI	Electric Power Research Institute	QSL	Qualified Supplier List
NEI	Nuclear Energy Institute	SCAQ	Significant Condition Adverse to Quality
NOS	Nuclear Oversight	SSC	Structure, System or Component
NQML	Nuclear Quality Management Leadership	SER	Safety Evaluation Report
NUPIC	Nuclear Utilities Procurement Issues Corporation	TR	Technical Report