# Utilization of ISO 9001 and Other Non-nuclear Suppliers for Safety-related Applications

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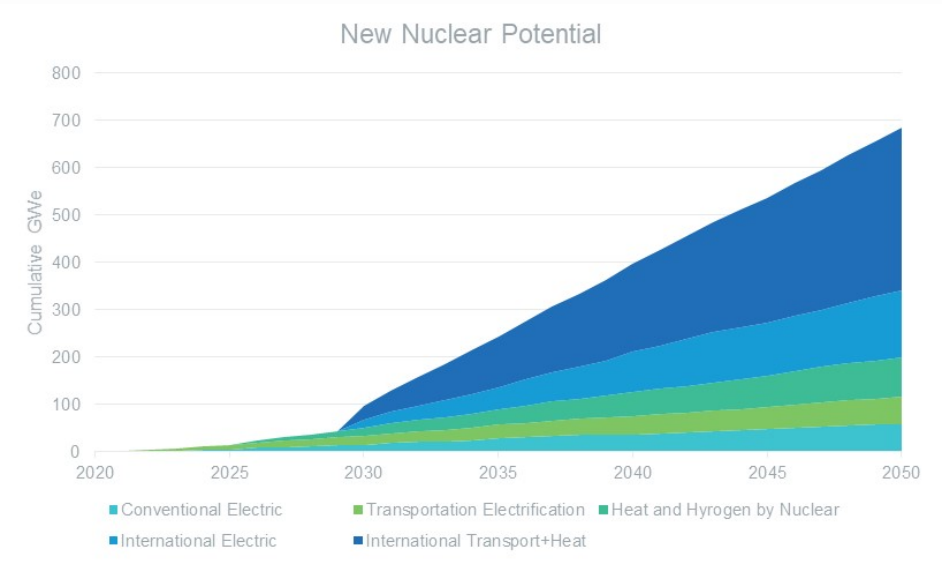
# What problem are we trying to solve?

- Increasing urgency for carbon reduction (electric and non-electric)
- Path to zero-carbon must be reliable and affordable
- Nuclear energy must be meaningful part of future energy portfolio
- Advanced reactor deployment plans are aggressive and urgent
- Deployment plans require additional suppliers



# Why focus on ISO 9001?

- There is a significant population of suppliers with ISO 9001 programs
- ISO 9001 is intended to be adaptable to any industry with the resulting level of programmatic rigor commensurate with industry demands
- As a result, many ISO 9001 suppliers have robust QA programs developed to supply reliable products of high quality to other industries
- Nuclear suppliers already accept items and services from ISO 9001 suppliers through their commercial grade dedication (CGD) process

# Why not focus on ISO 19443?

- Small population of Suppliers with ISO 19443 programs in comparison to ISO 9001
- The approach described in NEI 22-04 can be applied to various non-nuclear quality programs, including ISO 19443 programs
- NEI 22-04 includes an Appendix that describes how ISO 19443 addresses potential gaps and differences from ISO 9001 when compared to 10CFR50 Appendix B

# Why the NEI 22-04 approach instead of CGD?

- The CGD process does not define a path for the non-nuclear supplier to become a nuclear supplier
- The approach described in NEI 22-04 defines a path for a non-nuclear supplier to become a nuclear supplier and is intended to attract new suppliers into the nuclear industry
- The approach focuses on satisfying design requirements for procured items instead of developing a list of critical characteristics based on safety function

# Building on Foundation of Previous Work

- NRC SECY-03-0117 “Approaches for Adopting More Widely Accepted International Quality Standards” compares ISO 9001-2000 against the existing 10 CFR Part 50 Appendix B requirements and assesses the viability of four approaches
- EPRI 1007937 “Analysis and Comparison of ANSI/ISO/ASQ Q9001:2000 with 10CFR50 Appendix B: ISO 9001 Gap Analysis” and EPRI 1002976, “An In-Depth Review of Licensee Procurement Options for Use with ISO 9001 Suppliers”
- Other regulated industries utilizing an ISO 9001 based quality program and their regulating bodies have recognized the need for and implemented supplemental requirements and actions

# Building on Foundation of Previous Work

NRC SECY-03-0117 concludes:

- Using ISO 9001 as an alternative to Appendix B is not acceptable
- Other regulated industries considering ISO 9001 recognized the need for supplemental requirements and developed a sector-specific ISO standard
- One suitable approach is to provide additional controls, such as supplemental procurement requirements and actions, where necessary to satisfy the requirements of 10CFR50 Appendix B
- NEI 22-04 provides guidance for determining the gaps and differences with, and the supplemental requirements and actions needed to satisfy Appendix B

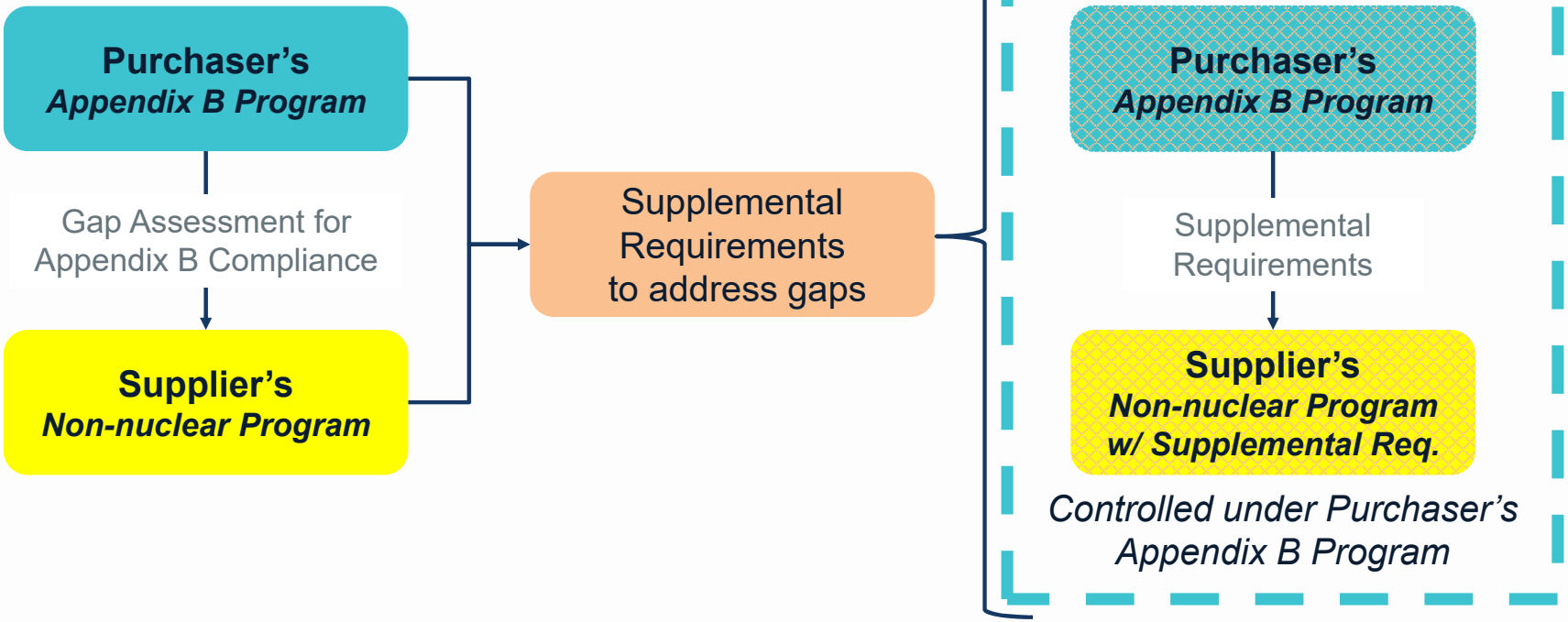
# Content from NEI 22-04

- High-level approach for implementation
- Gap Analysis for ISO 9001:2015 compliance to 10CFR50 Appendix B
  - Decomposes each Appendix B criterion into discrete requirements and identifies comparable requirements from ISO 9001
  - Identifies potential gaps for compliance with the regulation and differences in practice
  - Provides recommended supplemental requirements to address the gaps *(recommendations are suggested but not considered mandatory)*
- Options for Part 21 compliance
- Nuclear Safety Culture considerations
- Detailed steps for implementation

# High-level approach from NEI 22-04

*Approach can be applied to various non-nuclear programs*
*NEI 22-04 focuses on ISO 9001*




Implement supplemental requirements as needed to ensure procured items are suitably controlled under the Purchaser's Appendix B program

# High-level approach from NEI 22-04

## Division of Key Responsibilities

*(not intended to be all inclusive lists)*

**Purchaser's**
***Appendix B Program***

- Establish suitability of design
- Impose applicable procurement requirements to satisfy Appendix B
- Provide Supplier oversight, as needed to ensure requirements are satisfied
- Accept procured items as basic components
- Maintain responsibility for Part 21

**Supplier's**
***Non-nuclear Program w/ Supplemental Req.***

- Provide Purchaser access to design and manufacturing information
- Manufacture products to satisfy design requirements
- Control and notify Purchaser of changes to design of contract items
- Control and notify Purchaser of nonconforming contract items

*Supplier processes are considered an extension of the Purchaser's program*
*Thus, Supplier activities are controlled under the Purchaser's Appendix B Program*

# High-level approach from NEI 22-04

## Transition to Nuclear Supplier

*(not intended to be all inclusive lists)*

**Supplier's**
***Non-nuclear Program w/ Supplemental Req.***

- Demonstrate ability to satisfy procurement requirements under Purchaser's controls
- Update or supplement non-nuclear program to address gaps for Appendix B compliance
- Establish nuclear safety culture
- Update and establish procedures to comply with Part 21

**Nuclear Supplier's**
***Appendix B Program***

- Complies with applicable Appendix B requirements
- Complies with Part 21
- Ready to audit and be qualified to supply basic components

# Gap Analysis Examples

| **10CFR50, Appendix B, Criterion II** *(excerpt)* | **ISO 9001:2015** |
|---|---|
| The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix.<br><br>This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. | **4.4 Quality management system and its processes**<br><br>**4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.<br><br>**4.4.2** To the extent necessary, the organization shall:<br>a) maintain documented information to support the operation of its processes;<br>b) retain documented information to have confidence that the processes are being carried out as planned.<br><br>**8.5 Production and service provision**<br><br>**8.5.1 Control of production and service provision**<br><br>The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:<br>a) the availability of documented information that defines:<br>1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;<br>2) the results to be achieved; |

# Gap Analysis Examples

**Fundamental Requirement from 10CFR50, Appendix B:**

To establish a QA program in time to accomplish activities in accordance with applicable requirements, which is documented by written policies, procedures, or instructions and complies with the regulation.

**ISO 9001 Comparison**

ISO 9001 requires a quality management system to be established that includes documented information as needed to ensure the requirements of the ISO standard are satisfied, required processes are implemented properly, and the desired results are achieved.

**Potential Gap(s):**

ISO 9001 does not identify specific policies, procedures, or instructions that are required to be documented and nuclear regulatory requirements are not considered by most ISO suppliers. As a result, some ISO supplier programs are not documented sufficiently for nuclear applications. However, many ISO suppliers have well documented programs that address quality program attributes comparable to the regulation.

**Recommendation(s)** (if not addressed within the Supplier's program)**:**

The Purchaser could require submittal of project-specific procedures. However, that may not be practical for programs with only a few documented instructions. ISO suppliers that do not have well documented programs are unlikely to be good candidates for acceptance based on their program.

# Gap Analysis Examples

| **10CFR50, Appendix B, Criterion III** *(excerpt)* | **ISO 9001:2015** |
|---|---|
| The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.<br><br>The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization.<br><br>Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions.<br><br>Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in-service inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests. | **8.3.4 Design and development controls**<br>The organization shall apply controls to the design and development process to ensure that:<br>a) the results to be achieved are defined;<br>b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;<br>c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;<br>d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;<br>e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;<br>f) documented information of these activities is retained.<br><br>**8.3.5 Design and development outputs**<br>The organization shall ensure that design and development outputs:<br>c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;<br>d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. |

# Gap Analysis Examples

**Fundamental Requirement from 10CFR50, Appendix B:**

To perform independent verification of the design, by design review, alternate calculation, or testing a prototype under the most adverse conditions and to apply design control measures to activities such as reactor physics, accident analyses, material compatibility, in-service inspection, and acceptance criteria for inspections and tests.

**ISO 9001 Comparison**

ISO 9001 requires design verification and validation activities (i.e., the result of an inspection or test or other form of determination, such as alternate calculations or reviews) to ensure the design outputs meet the input requirements and to ensure the products and services meet the requirements for the specified application or intended use. ISO 9001 also requires design outputs to define requirements for monitoring and measuring and the acceptance criteria.

**Potential Gap(s):**

ISO 9001 does not require verification and validation activities to be performed by persons other than those that performed the design and does not explicitly require testing to consider the most adverse conditions. ISO suppliers do not address nuclear safety applications in their QMS scope and do not have the knowledge needed to ensure the design is suitable for a nuclear application.

**Recommendation(s)** (if not addressed within the Supplier's program)**:**

The Purchaser must retain responsibility for ensuring suitability of the design and impose nuclear industry specific requirements in the contract, as applicable.

# Gap Analysis Examples

| **10CFR50, Appendix B, Criterion IV** *(excerpt)* | **ISO 9001:2015** |
|---|---|
| To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix. | **8 Control of externally provided processes, products and services**<br>**8.3.4 Type and extent of control**<br>The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall:<br>a) ensure that externally provided processes remain within the control of its quality management system;<br>b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;<br>c) take into consideration:<br>1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;<br>2) the effectiveness of the controls applied by the external provider;<br>d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. |

# Gap Analysis Examples

**Fundamental Requirement from 10CFR50, Appendix B:**

To the extent necessary, require contractors or subcontractors to implement a quality assurance program that complies with 10CFR50, Appendix B.

**ISO 9001 Comparison**

ISO 9001 requires the organization to ensure externally provided processes do not prevent the organization's ability to deliver conforming products and services, which includes ensuring that externally provided processes remain in control and applying controls or verification activities, as needed, based on the potential impact the external provider has on the product or service and the effectiveness of the controls applied by the external provider.

**Potential Gap(s):**

ISO 9001 does not require procurement documents to impose a QA program that, to the extent necessary, complies with 10CFR50, Appendix B. ISO suppliers typically subcontract items and services to suppliers with non-nuclear quality programs that do not comply with 10CFR50, Appendix B.

**Recommendation(s)** (if not addressed within the Supplier's program)**:**

The Purchaser must assess whether the supplier adequately controls products and services under their program, including their controls applied to subcontracted activities, to ensure applicable requirements are satisfied. The Purchaser may need to supply qualified materials or require the use of Purchaser approved suppliers for subcontracted items and services that are not adequately controlled.

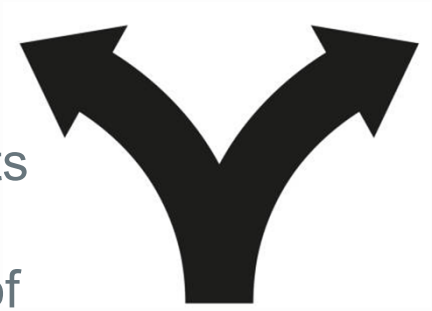
 

# Compliance with 10 CFR Part 21

**Two Options for compliance with 10 CFR Part 21**

**Option 1** *(likely first step)*:

- Supplier implements non-nuclear program with supplemental requirements
- Supplier procedures considered as extension of the Purchaser's program
- Supplier activities are controlled under the Purchaser's Appendix B program
- Purchaser maintains responsibility for Part 21



**Option 2:**

- Supplier updates program to comply with Appendix B and Part 21
- Supplier establishes nuclear safety culture
- Supplier is qualified by audit as nuclear supplier
- Supplier accepts responsibility for Part 21

# Nuclear Safety Culture Considerations

- Not a requirement from Appendix B or Part 21 but important commensurate with the safety significance of activities performed

- The Supplier's culture *(e.g., behaviors that drive program implementation)* is a factor for consideration in determining whether the Supplier is capable of complying with applicable requirements or becoming a nuclear supplier

# Detailed Steps for Implementation

1. Purchaser implements screening process *(optional)*
2. Purchaser performs on-site gap assessment
3. Purchaser and Supplier determine supplemental requirements to close gaps
4. Purchaser issues contract with supplemental requirements
5. Supplier executes the contract
6. Purchaser implements oversight activities, as needed
7. Supplier delivers the procured items
8. Purchaser verifies requirements satisfied and accepts delivery
9. Purchaser maintains supplier qualification (e.g., audits)
10. Supplier updates program to fully satisfy regulatory requirements *(optional)*
11. Supplier establishes nuclear safety culture *(optional)*
12. Purchaser qualifies Supplier as a Nuclear Supplier *(optional)*

# Screening Process *(Optional)*

- Useful tool to estimate level of effort to implement supplemental controls for compliance with 10CFR50 Appendix B
- More significant potential gaps are:
  - Supplier's program not documented sufficiently for nuclear applications
  - Supplier's culture not suitable for a nuclear application
  - Design change control process not defined
  - Significant activities are subcontracted
  - Special process controls are not suitable
  - QA functions, such as inspections and tests, are not sufficiently defined or independent

# Screening Process *(Optional)*

**Suggested screening questions:**

1. Can Supplier provide copies of certifications to industry standards, quality manual and an index of supporting procedures?
2. Does Supplier provide products to other industries with similar demands for safe and reliable equipment?
3. Does Supplier's program define a process for design change control?
4. What types of items or services are subcontracted by the Supplier? How are subcontracted activities controlled?
5. Does the Supplier perform special processes? How are they controlled?
6. Does the Supplier perform inspections, tests, or NDE? How are activities controlled?

**Based on the screening process results, the Purchaser and Supplier can assess whether the business case warrants proceeding with an on-site gap assessment.**

# On-site Gap Assessment

- Determines how non-nuclear program compares to 10CFR50 Appendix B
- Performed in a manner similar to an audit
  - Performance based assessment – documentation reviews and witnessed activities
  - Team lead is qualified Lead Auditor with sufficient experience to judge whether Appendix B requirements are satisfied
  - Technical Specialists (engineering involvement) included as needed to judge technical capabilities and controls
- Uses Gap Assessment Checklist developed from Appendix B requirements
- Identifies gaps for Appendix B compliance, not a commercial grade survey
- Findings only noted if program violations are identified, not for gaps

# Determine Supplemental Requirements

- The Purchaser and Supplier work together to determine the actions and supplemental requirements needed to close the identified gaps.
- Supplemental requirements likely result in a combination of supplemental instructions (e.g., QA Procedures, Plans, etc.) developed by the Supplier and supplemental procurement requirements imposed by the Purchaser.
- Recommendations for closing potential gaps are provided in NEI 22-04
  - These recommendations are not intended to be mandatory.
  - The Purchaser is responsible for determining the appropriate actions needed to close each gap identified in the gap assessment.
  - The list of gaps identified in a given gap assessment may differ from the list of potential gaps provided in NEI 22-04.

# Contract Execution and Oversight

- Purchaser issues contract with supplemental requirements and hold / witness points imposed as needed to ensure supplemental requirements are satisfied
- Supplier executes contract in accordance with the procurement documents, including the Supplier's non-nuclear quality program and the supplemental requirements.
- Purchaser performs source surveillance activities as needed to ensure the Supplier implements the supplemental requirements properly and controls items in accordance with the applicable requirements of Appendix B
- Supplier notifies Purchaser of nonconforming conditions associated with the contract

# Item Delivery and Acceptance

- Supplier delivers the procured items in accordance with the procurement requirements
- Purchaser verifies that the procurement requirements were satisfied and accepts delivery of the procured items
- Items become Basic Components upon acceptance by the Purchaser

# Maintaining Supplier Qualification

- Purchaser continues to perform surveillance activities for items on future contracts
- Purchaser performs annual performance assessments and triennial audits to ensure the Supplier maintains the ability to implement their non-nuclear quality program and the supplemental requirements
- The extent and frequency of oversight implemented by the Purchaser should be commensurate with the Supplier's level of performance and the complexity / importance of the items supplied

# Transition to a Nuclear Supplier *(optional)*

- Supplier, with assistance from the Purchaser or a consultant:
  - Updates their non-nuclear quality program to fully satisfy both 10CFR50 Appendix B and 10 CFR Part 21
  - Establishes a nuclear safety culture
- Purchaser audits the Supplier for compliance with 10CFR50 Appendix B and 10 CFR Part 21
- Upon completion of a successful audit, the Supplier is qualified as a Nuclear Supplier and can accept Part 21 responsibility

# Pilot Assessment #1

The pilot assessment was performed to determine the gaps in program requirements.

- Supplier program based on ISO 9001-2015
- Well defined, documented, and structured Quality Program
- Items that require resolution:
  - Independent Verification not established as part of the design program
  - Product testing requirements may need to be enhanced
  - M&TE controls will need to be better defined
  - Sub-supplier oversight
  - 10 CFR Part 21

The NEI checklist facilitated successful assessment, including identification of the program differences

# Pilot Assessment #2

The pilot assessment was performed to determine the gaps in program requirements.

- Supplier program based on ISO 9001-2015
- Well defined, documented, and structured Quality Program met ISO 9001 with some aspects closely aligned to 10CFR50 Appendix B
- Gaps that require resolution by customer agreement:
  - While this supplier had Engineering capabilities and by procedures appeared appropriate, implementation could not be evaluated as POs used were all build to print only
  - Testing requirements were enhanced by the customer POs
  - Sub-supplier controls addressed by PO restrictions and/or using Suppliers as directed on a case by case with Purchaser's appropriate direction
  - 10 CFR Part 21 process in draft but not fully implemented

# Status and Next Steps

- NEI 22-04 “Utilization of ISO 9001 and Other Non-nuclear Suppliers for Safety-related Applications” will be informed by industry and pre-submittal meeting feedback, including ISO 9001 supplier dry run assessments and broad industry review (Q3 2023)
- NEI participates in pre-submittal meeting with NRC (Q3 2023)
- NEI submits for NRC review and endorsement (Q4 2023)

# Questions?

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