

Case Study of Risk-Based Quality Management for On-time Delivery of i-SMR Licensing Documents

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1. Introduction

Developing licensing documents for an SMR standard design entails substantial schedule and quality risks because multi-organization collaboration, regulatory compliance, and cross-document linkage or traceability must be achieved simultaneously. In particular, degradation of input quality (technical bases, references, and interfacing deliverables), inconsistency in document currency, and gaps between existing regulatory requirements and emerging SMR-specific design features are major drivers of rework and review delays that directly threaten a fixed deadline.

Despite the practical importance of timely licensing-document development in nuclear programs, prior discussions have often focused on schedule control at the operational level rather than on how document quality risks should be systemically managed under a fixed regulatory timeline. In regulation-intensive and multi-organizational environments, delays are not caused only by writing capacity, but also by fragmented technical inputs, unclear ownership across organizations, and unresolved regulatory gaps. However, these issues have rarely been framed analytically as a risk-based quality management problem.

Accordingly, this study aims to examine how a risk-based quality management approach could support the timely delivery of i-SMR licensing documents in a multi-organizational program environment. Specifically, this study addresses the following questions: (1) What major quality-related risk factors affect the timely delivery of licensing documents? (2) How can these risks be systemically managed through structured coordination, input control, and gap analysis? and (3) What academic and practical implications could be derived from this case?

This paper presents a case study of a risk-based quality management approach applied to a licensing-document development program involving approximately 40 industry-academia-research organizations, with the objective of delivering all three documents by Dec. 31, 2025.

2. Methods and Results

This study adopts a case study approach to analyze how risk-based quality management supported the

timely delivery of licensing documents under a fixed regulatory deadline. The analytical focus was placed on four dimensions of risk: regulatory requirements, input data, inter-organizational dependencies, and review/rework.

Project success is commonly constrained by three interdependent factors – scope, schedule, and cost – which often entail trade-offs [1]. In a multi-organization licensing-document program for i-SMR standard design, schedule slippage is not merely a delay in delivery; it amplifies quality risks by triggering review bottlenecks, rework, and missing or late interfacing inputs. Conversely, inadequate quality control increases revision and re-review cycles, rapidly deteriorating both schedule and cost performance. Accordingly, this study treats on-time delivery as a primary objective while defining the key control points as proactive assurance of input quality and traceability and early identification and closure of gaps between regulatory requirements and SMR-specific design features.

2.1 Risk frame and acceptance criteria

Risks were categorized using a Risk Breakdown Structure (RBS) across four dimensions shown in table 1:

Table 1: Risk Breakdown Structure (sample)

Regulatory requirements	regulatory gap
	interpretation changes / difference
	alternative / additional request
Input data	missing items / items that cannot be completed without inputs
	uncertain provenance
	outdated sources
	baseline freeze date
	citation errors
Inter-organizational dependencies	interface delays
	unclear scope or ownership
	restricted access
Review or rework	blanks / TBD
	insufficient evidence
	potential IP constraints
	cross-document inconsistencies

technical terminology / abbreviation unification

Practical quality acceptance criteria were fixed as completeness, consistency, traceability, and change control, and were implemented as checklists for intensive reviews and input verification.

2.2 Monthly program-wide coordination meeting with a single RAID/Action Item log

A monthly coordination meeting consolidated progress using a unified definition of progress and completeness. All decisions and follow-up tasks were captured in a single Action Item log with explicit session number, target research, details, request-owner dependencies, and action deadlines linked to relevant risks.

When predefined triggers occurred (e.g., delay beyond 28 days or non-delivery of critical inputs), items were escalated from action item to risk. Then, priorities and mitigation actions for the issue were rebalanced or re-addressed at the next meeting.

Session	Target Research	No.	Details	Request	Owner	Action deadline	Completion date	Termination
6th	ALL	AI 6.1	Request for review of EWS (scaled based performance by A design of conditions for each group subcommittee, 1.5	CR	ALL	24.12.31	X	X
6th	ALL	AI 6.2	Adjustment Section 6.2-1: Electrical Engineering (management of project management organizations including external	CR	ALL	24.12.16	24.12.31	O
7th	2-6-2	AI 7.1	AI Memo request for Instrument and Neutron Detector shape and dimension data	IMP	CR24-20	25.1.31	X	X
7th	ALL	AI 7.2	Confirmation of meeting schedule for design issues of main steam and main water supply systems according to the application of through-flow type SG	CR	GSJ	25.1.31	25.2.4	O
7th	ALL	AI 7.3	Provide the 3rd draft of the licensing document	AE	ALL	25.1.31		O
8th	ALL	AI 8.1	Presentation of the status of verification reflecting the opinion of the regulatory body	CR	AE	next meeting	next meeting	O
8th	ALL	AI 8.2	Preparation of detailed plans for reducing radiation sources in the event of major accident and an optimal plan for D2 assessment	IMP	GSJ	next meeting	next meeting	O

Fig. 1. Example of coordinate meeting action item

2.3 Control of interfacing technical inputs (Input Register) and an input-quality procedure

Shared technical inputs across organizations were registered and controlled through an Input Register (table 2). A formal procedure verified completeness, currency, suitability, traceability, and consistency of inputs and references so that provenance ambiguity, version confusion, and citation errors were blocked before they propagated into drafts and triggered rework (figure 2).

Table 2: configuration of Input Register

Content	Example
Input ID	1, 2, 3, ...
Applicable documentation	System Functional Description
Purpose	PSA for i-SMR
Request info.	<ul style="list-style-type: none"> Request Research project: 1-2-산 Request Organization: KAERI Category: PSA Deadline for requesting provision: Dec. 2024

Content	Example
Providing info.	<ul style="list-style-type: none"> Providing Research project: 1-7-산 Providing Organization: AE Category: System design Date of availability: June. 2025
Negotiation result	Under discussion
Offering present condition	Not yet
Renegotiation status	3rd meeting
Review / Revise or Alternative basis	Partial provide (March.2025)

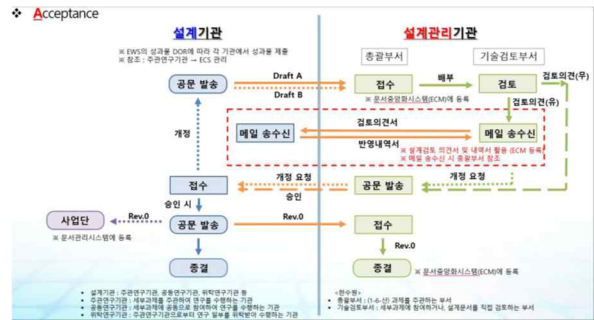


Fig. 1. Example of input-quality check procedure (acceptance)

2.4 Gap analysis between regulatory requirements and i-SMR-specific design features (Gap Log)

Regular gap analysis was institutionalized and managed via a Gap Log since 2023. As the standard design became more concrete, the gap analysis also became more detailed. Each gap item recorded the requirement and interpretation, SMR-specific feature, potential compliance issue, impacted document/section, mitigation strategy (evidence strengthening or additional analyses), target due date, and status (Open/In progress/Closed/On hold). This further strengthened the quality of the licensing documents, and shifted the posture from reactive responses to proactive preparation for likely regulatory concerns.

2.5 Milestone-based intensive reviews with line-by-line completeness verification

At each milestone, intensive review meetings verified completeness line-by-line and immediately converted missing or insufficient content into executable tasks by assigning owners, due dates, and countermeasures on the spot. Cross-document interfaces (assumptions, data, and evidence shared across SSAR/SDS/PAMP) were prioritized to prevent inconsistencies early.

KPIs were pre-defined with clear definitions, units, calculation rules, and data sources to eliminate variability in measurement across organizations and to enable early risk sensing based on monthly trends. In particular, input-quality indicators and the remaining

gap-issue ratio were treated as leading indicators for rework and schedule slippage; when triggers were detected, intensive reviews and priority rebalancing were activated.

As a result, document completeness reached 100 % by the deadline (Dec. 31, 2025), while the action-item closure rate was maintained at 100 % throughout the program.

3. Conclusions

This study presented a case of risk-based quality management applied to the timely delivery of i-SMR licensing documents in a multi-organizational program environment. The case showed that delivery performance was influenced not only by schedule control, but also by the disciplined management of input quality, traceability, regulatory-gap closure, and line-by-line completeness verification. As a result, the program achieved 100 % completion of licensing documents by the deadline, with a 100 % action-item closure rate and 100 % overall progress.

From an academic perspective, this study suggests that timely delivery of licensing documents in a regulation-intensive programs should not be understood solely as a scheduling issue. Rather, it can be interpreted as an outcome of risk-based quality management in which document completeness, consistency, traceability, and timely gap closure function as core control variables. In this sense, the case extends project management discussions by showing that schedule performance in complex licensing programs is closely coupled with quality assurance and inter-organizational governance.

From a practical perspective, this study provides a structured management approach combining an RBS-based risk frame, a unified RAID/Action item log, an Input Register, a Gap Log, and milestone-based intensive reviews. These mechanisms may be useful for other nuclear licensing programs or regulation-intensive engineering document projects involving multiple organizations and fixed deadlines.

This study is limited by its single-program scope. Future work should standardize KPIs across programs and explore automation tools for input and gap-issue management.

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REFERENCES

- [1] PMI, A guide to the Project Management Body of Knowledge (PMBOK Guide), 6th edition, Project Management Institute, 2017.