



# **Metrolinx System Review Panel (SRP) Terms of Reference (ToR)**

MX-SEA-TOR-001

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# Authorization

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# Documents

TABLE 0-1 SUPPORTING DOCUMENTS

Reference*	Document Title	Relation
CSA R114:22	Canadian Method for Risk Evaluation and Assessment for Railway Systems	Canadian Standard
BS EN 50126-1	Railway Applications. The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 1: Generic RAMS Process	International Standard
BS EN 50126-2	Railway Applications. The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 2: Systems Approach to Safety	International Standard
BS EN 50128	Railway applications – Communication, signaling, and processing systems – Software for railway control and protection systems	International Standard
BS EN 50129	Railway applications - Communication, signalling and processing systems - Safety related electronic systems for signalling	International Standard
ISO 15288	Systems and software engineering – System life cycle processes	International Standard
April 5, 2023	Metrolinx Safety Certification Committee Terms of Reference	Related ToR
MX-EAM-STD-01	Authority to Work Standard	Related Standard

\*Note: latest version shall apply unless otherwise specified contractually.

# Acronyms and Abbreviations

TABLE 0-2 ACRONYMS AND ABBREVIATIONS

Acronym	Full Name
AIP	Approval in Principle
CTC	Consent to Construct
CTO	Consent to Operate
CTT	Consent to Test
DPEL	Designated Project Engineering Lead
MSCC	Metrolinx Safety Certification Committee
RAM	Reliability, Availability, and Maintainability
RAMS	Reliability, Availability, Maintainability, and Safety
SDS	Single Design Solution (or Safety Design Solution, depending on PA)
SME	Subject Mater Expert
SRP	System Review Panel
SSRP	System Safety Review Panel

# 1. System Review Panel Terms of Reference

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## 1.1 Preamble

- 1.1.1 Metrolinx System Review Panels (the "SRP") are established under the authority of the Metrolinx Safety Certification Committee (the "MSCC").
- 1.1.2 The following constitutes the Terms of Reference (ToR) of the Metrolinx System Review Panel(s).
- 1.1.3 For the purposes of this document, both the Metrolinx System Review Panels and the Project or Program specific Metrolinx System Safety Review Panels are referred to using the acronym "SRP", as these Terms of Reference are applicable to both. Refer to section 1.10 of this ToR for details on the allocation of projects to different SRPs.

## 1.2 Purpose

- 1.2.1 The SRP is a decision-making and review body, accountable to MSCC, that makes recommendations and supports the functions of the MSCC.
- 1.2.2 The purpose of the SRP is to:
  - 1) review and endorse that any proposed significant change (as defined by the CMREA) to transportation infrastructure or operations that may affect the safety of the public or personnel or the protection of property or the environment is designed, constructed, commissioned and operated in an acceptable manner, by reviewing artifacts of the safety and system assurance process on behalf of the MSCC; and
  - 2) ensure that a project categorised as 'non-Significant' (as defined by the CMREA), provides an update to the SRP on how the project is progressing, upon request of the MSCC.
- 1.2.3 Any technical reviews completed by the SRP shall not absolve a proponent or applicant requesting certification or authorization from the MSCC of responsibility and liability for the change or system that is the subject of the certification or authorization request.
- 1.2.4 SRP operates in oversight to provide assurance that:
  - 1) projects are developed and delivered in compliance with the project requirements, applicable legislation, and national, industry, and applicable Metrolinx standards;
  - 2) operational performance, reliability, customer satisfaction, safety, and security risk have been appropriately identified, quantified as needed, and addressed;
  - 3) measures are in place to mitigate and/or minimize risks to as low as reasonably practicable (ALARP); and
  - 4) operational and maintenance readiness are achieved prior to commissioning.

## 1.3 Authority

- 1.3.1 The SRP Terms of Reference are established through the authority of the MSCC. In fulfilling its mandate, the SRP has the authority to:
  - 1) retain advisors, consultants, or experts it deems necessary including Independent Safety Assessors accredited by the Standards Council of Canada; and

- 2) seek any additional information or investigation it requires from an officer or employee of Metrolinx, a proponent making a submission for safety certification / safety authorization, or other relevant stakeholders.
- 1.3.2 The SRP shall not have authority to approve or withhold approval for any decision that rests with the MSCC unless specifically delegated.

## 1.4 Membership

1.4.1 **Composition** - The SRP shall be comprised of up to fifteen members and shall include:

- 1) the SRP Chair;
- 2) Professional Heads or Heads of Disciplines / Specialists (Subject Matter Experts "SME") required based on the System under consideration, one of whom may be appointed Deputy SRP Chair (refer to 1.4.4 for a list of common discipline representation);
- 3) the SRP Secretary (non-voting).

1.4.2 **Competence** - Members that constitute the SRP shall have the appropriate competence and level of authority required to be able to fulfil their requirements as a SRP member, notwithstanding the expectation of continuous improvement of their individual and collective knowledge regarding the activities of Metrolinx and the regulatory context in which it operates. As part of the competence requirements, the quorate SRP shall:

- 1) have a detailed understanding of the CSA R114:22- *Canadian Method for Risk Evaluation and Assessment for Railway Systems* (CMREA) including determination of significance, EN 50126-1, EN 50126-2, EN 50128, and EN 50129;
- 2) have a thorough understanding of the railway system(s) that are the subject of the SRP;
- 3) have experience in hazard identification processes;
- 4) have experience in risk management including risk evaluation and assessment and specifying safety requirements to mitigate risk;
- 5) be skilled at integrating information from various domain experts to identify system hazards and interfacing risks;
- 6) understand risk acceptance criteria and be able to choose the appropriate level of risk to demonstrate safety of the system;
- 7) basic knowledge and understanding of safety engineering; and
- 8) understand project life-cycle and Reliability, Availability, Maintainability and Safety (RAMS).

1.4.3 **Chairs** - The SRP Chair is accountable to the Metrolinx Chief Engineer. The Metrolinx Chief Engineer shall approve the appointed SRP Chair. When approving an SRP Chair, the Metrolinx Chief Engineer shall determine whether the proposed SRP Chair is deemed competent to undertake the role. Any nominated SRP Chair external to Metrolinx Engineering & Asset Management shall have Designated Project Engineering Lead (DPEL) status, appointed through the Metrolinx Authority to Work Standard [ref. MX-EAM-STD-01], using the form in Appendix A.1. In the absence of the SRP Chair, an Acting SRP Chair, deemed competent by the Metrolinx Chief Engineer, may be appointed, with approval by the Metrolinx Chief Engineer. The SRP Chair shall, in addition to the competence requirements of the SRP Members, as determined at the discretion of the Metrolinx Chief Engineer:

- 1) have extensive experience in interpreting legal and technical requirements and assessing compliance with such requirements;
- 2) be able to effectively assess other people's competence in system safety management;
- 3) have an understanding of the railway system that is the focus of the SRP;
- 4) be broadly conversant in the subjects to be discussed by the SRP;
- 5) be a staff member of Metrolinx; and
- 6) have experience chairing formal meetings.

1.4.4 **Discipline Representation** – The SRP Members shall adequately cover all technical, operational, maintenance and safety disciplines required to undertake the review activities. Heads of Disciplines may elect to delegate their SRP membership authority to a representative. Delegated SRP Members representing E&AM disciplines must be employed by Metrolinx within the E&AM department, or have appropriate DPEL status under the Authority to Work Standard [ref. MX-EAM-STD-01]. An SRP Member may represent one or more disciplines as long as the competence criteria are met. Such disciplines may include:

- 1) safety, health and environment;
- 2) train control, signals and communications;
- 3) track;
- 4) electrification;
- 5) civil infrastructure;
- 6) fleet;
- 7) maintenance;
- 8) operations; and
- 9) systems engineering.

## 1.5 Meetings and Procedural Matters

1.5.1 **First Panel Meeting Procedure** – At the first meeting, the SRP Members shall collectively agree upon the SRP Mandate (refer to section 1.9 for detail) for approval by the Chief Engineer.

1.5.2 **Frequency of Meetings** – The SRP shall meet at a regular time each month, unless otherwise agreed by the SRP and documented in the SRP mandate (refer to section 1.9 for detail). All members or delegates are expected to be available for each meeting and actively participate when required by the subject matter. A meeting may be held remotely as required to enable all members to communicate adequately with each other during the meeting. Additional meetings may be scheduled by the SRP as warranted. In the event that the volume of material overwhelms the SRP such that SRP is not able to adequately fulfill the mandate, the SRP shall notify the MSCC.

1.5.3 **Functions of SRP Meetings** – The SRP meeting may function as:

- 1) a regular monthly progress update and review of draft submission material for information and project guidance from the SRP; or
- 2) a formal submission for decision for the SRP to endorse the submission to the MSCC.



Individual SRP meetings may include multiple functions on one agenda for different projects within the SRP Mandate.

The MSCC may require specific representation at SRP meetings reviewing formal submission for decision. Any such requirements shall be documented in the SRP Mandate.

- 1.5.4 **Agenda and Meeting Materials** – A written agenda for each SRP meeting, together with any related materials, shall be distributed to the SRP Members at least five (5) working days in advance of the meeting date. The agenda shall include time for review of the Action Log from prior meetings.
- 1.5.5 **Submissions for review by SRP** – Submissions for review by the SRP must be received by the SRP Secretary a minimum of 10 working days prior to the SRP meeting to allow pre-review and distribution. The SRP Chair may use their discretion to amend the minimum amount of days required for submission of large and/or complex submissions. The SRP Secretary will communicate the amended deadlines to the submitters and the panel. The submission shall consist of:
- 1) a brief project overview, including what the project is asking from SRP and the project's lead Subject Matter Expert ("SME") recommendation;
  - 2) an Independent Safety Assessor ("ISA") report for the submission (as applicable in accordance with CMREA);
  - 3) the submission material in accordance with the Project Agreement (or as otherwise agreed);
  - 4) any other relevant supporting documentation.
- 1.5.6 **Quorum** – The presence of four or more SRP Members fulfilling the competence requirements as per 1.4.2, at least one of whom shall be SRP Chair, constitutes quorum for an SRP meeting.
- 1.5.7 **Consensus and Voting** – To the extent that decisions may be rendered by the SRP, the SRP shall strive to achieve consensus at the meeting of all voting SRP Members in attendance. For the purposes of these Terms of Reference, consensus includes an attempt to resolve all objections and the identification of conditions that any agreement would be subject to.
- Should a resolution within the SRP meeting not be possible then dedicated meetings involving the project and appropriate members of the SRP may be required, with written submission by the objecting panel member(s) of the issue and the rationale for all objections as an input to the dedicated meetings. The conclusion of these sessions shall be referred back to a quorate session of the SRP for consideration.
- Any matter for which consensus cannot be achieved, following any necessary dedicated meeting(s), may be put to a vote to be decided by a majority of the votes cast. In such instances, each member, including the SRP Chair, has one vote. In the event of an equality of votes, the SRP Chair has the deciding vote. Motions shall be moved and seconded, with individual votes and any objections noted by the SRP Secretary in the meeting minutes.
- The SRP endorsement report to MSCC will address the objections made and include the actual objection. The conclusion documented in the SRP report to MSCC will set out the rationale for the SRP position including any remaining concerns and risks.
- In general, any SRP Member having objections with a decision made at an SRP meeting may register their objection at the meeting and then support this with a written submission via e-mail to the SRP Secretary of the issue and the rationale for their objection. These will be

addressed by the Chair, normally as part of the above activity. Objections will also be periodically reported to MSCC to confirm they have been addressed.

- 1.5.8 **Minutes and Action Log** – The SRP Secretary shall document the minutes of the meeting, including an Action Log that documents any tasks, items for further review, requests for information, or report-back requirements. No later than five (5) business days after the SRP meeting, the minutes shall be distributed to the SRP Members and sent to the MSCC Secretary for filing.
- 1.5.9 **Rules of Order** – The SRP is accountable to those submitting to the SRP for objective and impartial conduct; clarity of process, decisions made and actions; and timely response. Robert’s Rules of Order, latest edition, shall apply to the conduct and regulate discussion of the Metrolinx SRP.

## 1.6 Duties and Responsibilities

- 1.6.1 **General** - The SRP shall:
- 1) assess and accept evidence which demonstrates the overall operational, environmental and technical quality of the railway on behalf of the MSCC that will allow projects to progress through set gates during the project (see section 1.8 for detail)
  - 2) review, evaluate, accept and make recommendations on the system assurance submissions, considering their integration with the wider transportation network (including interfaces between heavy and light rail systems), in order to manage system and safety requirements, processes and risks;
  - 3) provide endorsement of technical decisions that would result in route wide precedents or changes to the current program and cost baseline;
  - 4) make decisions within the delegated authority of the SRP as agreed with the MSCC;
  - 5) manage the portfolio of projects specified within the SRP Mandate and monitor progress on submissions and actions to completion; and
  - 6) provide an escalation route to the MSCC.
- 1.6.2 **Non-Significant Projects** – If, either as a result of an audit by Metrolinx or a project’s internal process, it becomes apparent that a project that had previously been categorised as ‘non-Significant’ becomes ‘Significant’, the SRP shall notify the MSCC of the need to reclassify the project.
- 1.6.3 **Reporting Responsibilities** – In advance of a request for certification or approval from the MSCC, the SRP shall:
- 1) review all safety and system assurance documentation prepared by the proponent or applicant comprising the submission to the MSCC;
  - 2) review all Independent Safety Assessor (ISA) reports accompanying the submission to the MSCC; and
  - 3) make a recommendation to MSCC on certification or approval.
- 1.6.4 **Review of SRP Mandate** – The SRP shall review and assess the adequacy of the SRP Mandate at least annually.
- 1.6.5 **Self-assessment** – An evaluation of the SRP shall be conducted regularly, at a minimum annually, to review its performance for the purpose, among other things, of assessing its effectiveness, whether the panel has fulfilled the responsibilities and duties stated in these

Terms of Reference, and the timeliness of decisions rendered by the SRP. Results of the SRP self-assessment shall be submitted to the MSCC.

- 1.6.6 **Inter Panel Reporting** – The SRP Chair shall bring any activities that overlap with the Mandate of any other SRP to the attention of the other SRP and to the MSCC Secretary.

## 1.7 Duties and Responsibilities of Members

- 1.7.1 The SRP Chair shall submit regular reports, in accordance with the Mandate, to the MSCC.
- 1.7.2 In the case that Heads of Disciplines have delegated their SRP membership to a Designated DPEL (appointed through the Metrolinx Authority to Work Standard [ref. MX-EAM-STD-01]), the Heads of Disciplines, or deputy, shall be available to attend all SRP meetings and shall be in attendance for all SRP meetings where a formal submission for decision exceeds the delegated authority of the DPEL.
- 1.7.3 SRP members can advise on the system and safety assurance approaches and proposed resolution of actions, however, the project is responsible for undertaking all evaluations and assurance activities.
- 1.7.4 SRP Members in exercising their powers and performing their duties, shall:
- 1) act honestly and in good faith with a view to protecting the safety of the public, workers, property and the environment;
  - 2) prepare for, attend, and actively participate in SRP meetings;
  - 3) perform their duties in a manner that public trust in the integrity, objectivity, and ethical conduct of decisions related to safety and decision of Metrolinx, is conserved and enhanced;
  - 4) advise the SRP of any perceived or actual conflict of interest situations related to an agenda item and withdraw from discussion of that particular agenda item where appropriate;
  - 5) exercise care, diligence, and professional judgment that would be reasonably expected of an individual in comparable circumstances; and
  - 6) comply with the SRP Terms of Reference and applicable SRP Mandate.

## 1.8 Submission Gate Endorsement

- 1.8.1 The formal submissions for decision to SRP will typically happen at five key stages through the project life cycle, though this may vary depending on the stage of the project coming to SRP, and the project contractual submission terms:
- 1) Submission for Acceptance in Principle (AIP) endorsement, which typically covers the activities and deliverables in EN 50126-1:2017 life cycle phases 1 through 3.
  - 2) Submission for Single Design Solution (SDS) endorsement, which typically covers the activities and deliverables in EN 50126-1:2017 life cycle phases 4 and 5. (note: some contracts call this submission gate “Safety Design Solution (SDS)”).
  - 3) Submission for Consent to Construct (CTC) endorsement, which typically covers the activities and deliverables in EN 50126-1:2017 life cycle phase 6.
  - 4) Submission for Consent to Test (CTT) endorsement, which typically covers the activities and deliverables in EN 50126-1:2017 life cycle phase 7.

- 5) Submission for Consent to Operate (CTO) endorsement, which typically covers the activities and deliverables in EN 50126-1:2017 life cycle phases 8 through 10.

## 1.9 SRP Mandate

1.9.1 The SRP Mandate shall include, as a minimum:

- 1) The objective(s) and scope of the SRP;
- 2) The portfolio of projects under review by the SRP;
- 3) The authority delegated by the MSCC, including any specific exclusions;
- 4) The composition of the panel including details of panel member discipline representation, Authority to Work arrangements, and any requirement for MSCC delegated representation;
- 5) The frequency and timing of the regular SRP meetings;
- 6) The arrangements for meeting minutes and record keeping;
- 7) The plan for regular reporting from the SRP chair to the MSCC;
- 8) Any specific addendums and agreed variations to the SRP Terms of Reference; and
- 9) Reference to the appropriate SRP meeting minutes for the record of acceptance of the SRP Mandate by the panel.

1.9.2 All SRP Mandates shall be submitted for acceptance by The Engineering and Asset Management (E&AM) Systems Engineering Assurance (SEA) team and for approval to the Chief Engineer.

## 1.10 Allocation of Projects to Different SRPs

- 1.10.1 The SEA team oversees the integration and allocation of projects to all SRPs, facilitates the production of SRP Mandates, and consults with projects to confirm the allocation of projects, their boundaries, and interfaces. Allocation of projects to different SRPs will normally consider the profile of the integration risks presented by the themes of Technology, Geography and Operational changes and where appropriate the commercial or contractual arrangements.
- 1.10.2 The SEA team holds the register of SRP Mandates and their approval status.
- 1.10.3 The SEA team maintains a log of all railway projects which confirms the allocated SRP, the nominated VP representing E&AM on the panel, and the risk-based assurance regime categorization. This log also holds the planned dates for formal SRP gate submissions, as available. All projects shall remain as allocated until this SEA log is updated.
- 1.10.4 All changes to the allocation of projects, including the establishment of new panels shall be reported to the Metrolinx Safety Certification Committee.
- 1.10.5 The director of SEA, or delegate, chairs an SRP (referred to as "the SEA SRP" below):
  - 1) The SEA SRP is the default SRP for all projects should the allocation be disputed or require detailed consideration.
  - 2) The SEA SRP will normally own projects that make network wide alterations to operational practice and/or introduce new technology and working practices for Metrolinx owned assets. This may be at a principle level with specific applications endorsed by project specific SRPs.

- 1.10.6 The SEA team must be notified at [SRP.Secretary@metrolinx.com](mailto:SRP.Secretary@metrolinx.com) of changes to the allocation of projects and may escalate any concerns to the SEA SRP should the need arise.

Superseded

# Appendix A – Supporting Material

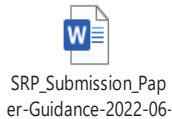
## A.1 Approval of a project or program specific SSRP Chair by the Chief Engineer

- A.1.1 The attached word document provides a template for nominating an SSRP Chair for approval by the Chief Engineer. Contact [SRP.Secretary@metrolinx.com](mailto:SRP.Secretary@metrolinx.com) for a form reference number.



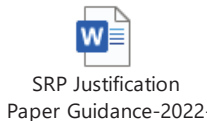
## A.2 SRP Submission Report

- A.2.1 The attached word document provides an outline and high level guidance for project submission reports to SRP.



## A.3 Justification for Commissioning Paper

- A.3.1 The attached word document provides an outline and high level guidance for project Justification for Commissioning Papers, to be used and customized as needed for projects, as determined by SRP on a case by case basis.



## A.4 SRP Report to MSCC (following submission for decision)

- A.4.1 The attached word document provides an outline and high level guidance for SRP Reports to MSCC endorsing forward a project submission for decision, to be customized as needed for projects based on contractual assurance process agreements and the conclusions of the SRP including any conditions.



# Appendix B - Guidance on typical assurance themes to structure the review by SRP

The following is intended as guidance for SRP chairs and panel members to consider in terms of scope of review and is not intended to replace any contractual requirements for scope of review by SRP. The applicability of these themes, in whole or in part, may vary depending on contractual requirements for SRP scope, where certain themes may be covered by different forums as an input to, or parallel process with, SRP. SRP chairs and panel members are encouraged to consider how these themes will be covered for the project(s)/program(s) under their scope of review, and to outline the arrangements to cover these assurance themes as part of the SRP objectives and scope documented in the SRP Mandate, per section 1.9.

## A.1 System Safety Assurance Theme

- A.1.1 This theme includes review to confirm to the appropriate level for the life-cycle stage and in accordance with the requirements of the specific project's contract:
- 1) That there is evidence of a coherent integrated engineering and safety compliant design (i.e. ESAC report) being delivered through whole project lifecycle.
  - 2) That the system definition is appropriate and aligns with the project categorisation.
  - 3) That the scope for the assessment, including systems, operations, and interfaces has been adequately defined.
  - 4) That all correct parties, stakeholders, and organizations have been involved in the process.
  - 5) That all hazards have been identified by competent teams, controlled, and hazard transfers complete.
  - 6) That Risk Assessments have been completed by competent teams, the correct principles applied and the extent of application sufficient.
  - 7) That all Safety Requirements are clearly defined (unambiguous), controlled, validated, traceable, and closed appropriately with sufficient and traceable evidence.
  - 8) That tests have demonstrated that product matches the specified requirements at each step.
  - 9) That all required certification has been completed, signed, and approved.
  - 10) That all residual issues have been captured and placed into a controlled process for closure.

## A.2 Technical Assurance Theme

- A.2.1 This theme includes review to confirm to the appropriate level for the life-cycle stage and in accordance with the requirements of the specific project's contract:
- 1) That all design work, including implementation of requirements, hardware, software and data have been properly reviewed and approved.
  - 2) That the required functions have been adequately described and criticality levels applied.



- 3) That the selected products meet the specified requirements and have been accepted for use.
- 4) That the appropriate safety analyses have been undertaken to assess the safety risk associated with the commissioning and to confirm that it is satisfactory.
- 5) That sufficient testing (including Factory Acceptance Tests and Integration Testing) has been successfully undertaken to confirm the system will function as required after installation.
- 6) That safety risk concerned with installation and commissioning is understood, with residual risk under adequate control.
- 7) That there are no concerns with respect to the competency of personnel undertaking all work, the quality and safety management processes followed, and appropriate record keeping of the work undertaken.

## **A.3 Operations and Maintenance Assurance Theme**

A.3.1 This theme includes review to confirm to the appropriate level for the life-cycle stage and in accordance with the requirements of the specific project's contract:

- 1) That there is sufficient evidence to ensure that the integrated design will meet the transportation system operational performance and maintainability requirements.
- 2) That all operational arrangements are correctly documented and any temporary working arrangements agreed.
- 3) That all maintenance arrangements correctly documented and any temporary working arrangements agreed.
- 4) That the required spares and/or technical support have been provided and arrangements for access agreed.
- 5) That all training been completed to support operational use.

## **A.4 RAM Assurance Theme**

A.4.1 This theme includes review to confirm to the appropriate level for the life-cycle stage and in accordance with the requirements of the specific project's contract:

- 1) That there is sufficient evidence to ensure that the integrated design will meet the system(s) RAM requirements throughout the whole project lifecycle.
- 2) That tests demonstrate that the selected products meet the specifications and requirements at each step.
- 3) Has a formal FRACAS process been established and accountabilities agreed.

## **A.5 Compatibility Assurance Theme**

A.5.1 This theme includes review to confirm to the appropriate level for the life-cycle stage and in accordance with the requirements of the specific project's contract:

- 1) That compatibility between the infrastructure(s) and the transportation vehicle(s) has been suitably demonstrated.



- 2) That compatibility with other transportation network infrastructure(s) has been suitably demonstrated.
- 3) That all correct stakeholders have been included in the process, including impacted 3rd parties (i.e. other impacted railway operators such as CN, CP, VIA, etc.).
- 4) That compatibility with other 3rd party equipment/neighbours has been suitably demonstrated.

## **A.6 Design Management Assurance Theme**

A.6.1 This theme includes review to confirm to the appropriate level for the life-cycle stage and in accordance with the requirements of the specific project's contract:

- 1) Requirements Management; that the requirements are clearly documented, tracked, traceable, and closed out as completed with agreement from the proponent.
- 2) Interface Management; that the interfaces are described clearly, with no scope gap for late changes, and managed through design completion and commissioning.
- 3) Engineering/Design Change Control; that all changes have been correctly managed, approval levels agreed and correctly applied, and change implementation monitored and aligned.
- 4) Configuration Management; that there are clear accessible records, with version, history, and rationale available to all and defining all changes precisely.
- 5) Verification & Validation; that tests demonstrate the system matches the requirements and specifications, completed as per plans with sufficient investigation of issues.