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RISSB
RAIL INDUSTRY SAFETY AND STANDARDS BOARD

Type Approval-Signalling

CODE OF PRACTICE

Draft - for Consultation

Notice to Users

Please note that this is a draft document for consultation.

Content may not reflect the content of the final published Code of Practice.

Document Control

Identification

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Document History

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1.1		Headings and outline
1.2	20 January 2017	First draft
1.3	14 February 2017	Incorporating DG comments
2	24 February 2017	Draft for Public Consultation

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Contents

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1 Purpose

This Code of Practice provides guidance on the application of AS 7702 for signalling products and promotes a common understanding of type approval requirements between suppliers of product for signalling applications and Rail Transport Operators (RTO) and Rail Infrastructure Managers (RIM).

2 Scope

This Code of Practice is intended to be applied to the type approval of signalling products. The following will be included within this Code of Practice:

(a) Guidance on which products needs to be type approved. (section 6, appendix 2)

(b) Detailed guidance on information to support type approval. (section 6.5)

(c) Scaling the type approval for the risks on the criticality. (sections 8, 9 & 10)

(d) Addressing incremental adjustments to existing type approvals. (section 8)

(e) Addressing incremental adjustments to grandfather approvals. (section 9)

(f) Application of provisional or interim approvals. (section 6.7.3)

(g) Identifying practices for trialling equipment during assessment. (section 7)

(h) Guidance on cross acceptance of products. (section 10)

3 Terms and Definitions

General railway technical terms can be referred to the Railway Operations - Glossary of Terminology.

For the purposes of this document, the definitions given in AS 7702 and the following apply:

Term	Definition
Derogation	A permanent non-compliance against an RTO specified requirement. All derogations shall be formally accepted approved by the RTO type approval authority with any necessary conditions to control the risk.
Engineering notification	A formal written communication to affected stakeholders for briefing to engineers and technical staff of a change to a product, the status of the approval and any checks required to verify that the product used is the version approved.
Evidence portfolio	A uniquely indexed portfolio, including all technical data, of verified evidence references associated with the submission to support a claim of compliance or derogations. Each item will have a unique index identification number specific to that portfolio to facilitate easy reference to the appropriate documentation supporting a compliance claim.

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Term	Definition
IRIS	International Railway Industry Standard. It is a globally recognized standard unique to the railway sector for the evaluation of management systems. IRIS is converting ISO/TS 22163 in 2017
ITR	Independent technical reviewer as defined in AS 7702.
Lead Engineer	The engineer that is responsible for defining the evaluation criteria, planning and managing the type approval process, coordinating between all stakeholders.
Product	This may be a single line interchangeable unit, software or system.
RFI	Request for information. Formal request for information in relation to compliance against a particular requirement.
Sponsor	The business unit of engineering organisation who supports the type approval from a business perspective and typically secures funding.
Supplier's representative	The engineer within the supplier's organisation that carries out the evaluation of their product against the RTO's criteria and justifies the claims of compliance with reference to verified evidence provides the derogation arguments and associated evidence for approval of any non-compliances.
Trial implementation plan	A plan to detail the objectives of the trial, roles and responsibilities and the inspection and tests evidence that shall be collected to support a further evaluation of the type approval with a view to full approval of the product under evaluation.
Type approval authority	An individual within an RTO with overall ownership and responsibility for type approval for a particular discipline, will typically take on the Independent Technical Reviewer Role and approve the evaluation criteria and the certificates and responsible for the ongoing maintenance of the type approvals. For a system product there may be more than one type approval authority for one for each discipline. This is assumed to be an existing accountability for a nominated individual within an RTO.
Type approval change form	This is an RTO specific form on which the type approval authority can formally record a justification for a limited type approval evaluation based on a notification of change from a supplier for inclusion in the product approval pack for any updated approval.
Type approval plan	A plan used to define the detail of a particular type approval, defining the responsibilities, evaluation criteria, trials and output for the type approval.

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Term	Definition
Type approval register	The register of all products that have been approved by the RTO accessible to all designers so that they can locate the certificates and conditions for type approval.
Type approval request form	This is a form on which to record the initial request by a sponsor to have a type approval considered for evaluation. This is for pre-approval to consider if a full evaluation is of benefit to the business and worth the time and effort.
Submission	This is the full submission of a type approval that has been accepted for evaluation, it is the supplier's submission of the technical data, evidence portfolio, product information pack and completed standards compliance register.

4 References

CENELEC. (2007, May 30). CLC/TR 50506-1:2007. *Railway Applications - Communication, Signalling and Processing Systems - Application Guide for en 50129 - Part 1: Cross-acceptance*. Europe: CENELEC.

RISSB. (2014). Rail Equipment Type Approval. *AS 7702*. Standards Australia.

Technical Programme Delivery Limited. (2013, December). International Engineering Safety Management Handbook - Volume 2. *Methods, Tools and Techniques for Projects*. TPD.

Technical Programme Delivery Ltd. (n.d.). International Engineering Safety Management Handbook.

5 Responsibilities

Responsibilities relating to type approval are defined in AS 7702 section 2.0, but at an organisational level. The following provides guidance on the roles within each of the organisations.

For all type approvals a type approval plan will be required that documents the specific responsibilities of individuals in relation to a particular product type approval.

5.1 Evaluating Rail Transport Operator (RTO)

5.1.1 General

The evaluating Rail Transport Operator is responsible for ensuring the requirements of AS 7702 are adapted and complied with for their particular operations. The evaluating RTO is responsible for the definition and approval of the evaluation criteria and for carrying out the evaluation based on the supplier evidence against the defined criteria.

There are two key roles defined for the evaluating RTO in this code of practice and the allocation of responsibilities may be handled differently by each RTO, providing the Independent Technical Review (ITR) role is maintained as required by AS 7702 2.4.

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It should be made clear in each type approval plan who is the ITR. It is possible that the lead engineer may delegate the evaluation of the product against the standards compliance matrix and the production of the type approval evaluation report.

5.1.2 Type approval authority

The type approval authority is, independent from the type approval evaluation.

The type approval authority is an individual with the authority to review the product type approval evaluation for a particular discipline. The type approval authority issues the type approval certificate for the product within their approval scope and confirms all application conditions that shall be complied with to assure the product is used for applications.

The type approval authority monitors the continued approval of products on the type approval register. There may be more than one type approval authority if the product is a system relevant to more than one engineering discipline.

Where it is not practical for the type approval authority to be independent from an evaluation then another competent individual shall take on the ITR role. Responsibilities, (a), (b) and (c) require an Independent Technical Reviewer (ITR) as defined by AS 7702.

The type approval authority responsibilities are-

(a) Carrying out the independent technical reviewer role, this responsibility may be delegated to another competent individual to carry out on their behalf;

(b) Validating the standards compliance register agreed between the lead engineer and the Supplier's representative**.**

(c) Approving, issuing and maintaining of the type approval certificates;

(d) Updating and maintaining the type approval register;

(e) Defining the audit scope and schedule for suppliers of safety critical and safety related products to assure the ongoing integrity of the product as per the original type approval;

(f) Monitoring the auditing of suppliers and the outcomes to of those audits in the context of continued type approval;

(g) Issuing improvement notices to suppliers and agree improvement action plans to support continued approval of their product;

(h) Deciding to suspend or withdraw type approval from a supplier;

(i) Agreeing action plans with suppliers to reinstate suspended type approvals;

(j) Reviewing change notifications by suppliers;

(k) Acting as the initial point of contact for unsolicited type approval applications; and

(l) Defining, documenting and maintaining a reference procurement specification for typical rail system products.

5.1.3 Lead engineer

This role is responsible, on behalf of the evaluating RTO, for identifying the evaluation requirements from risk assessments, technical requirements and existing specifications, coordinating between all stakeholders and will carry out the type approval evaluation.

The lead engineer can delegate responsibilities to other competent individuals as documented in the type approval plan.

The lead engineer shall be responsible for -

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(a) Ensuring the hazard analysis and risk assessment is complete for the proposed type approval scope and application contexts to assure all safety and interface requirements have been identified relative to the product and proposed application;

(b) Preparing the type approval plan;

(c) Defining the Scope of evaluation and the proposed application that limits the scope;

(d) Coordinating with the necessary representative within the RTO and the sponsor to confirm the technical, safety and business requirements for the product being considered for type approval;

(e) Coordinating between the type approval authority, the sponsor, the supplier's representative and other stakeholders to assure all are aware of the type approval and the range and quality of evidence required;

(f) Preparing the standards compliance register based on the requirements identified in the type approval plan for approval by the ITR;

(g) Reviewing the supplier evaluation of the product against the requirements as documented in the standards compliance register; and

(h) Preparing the product approval pack.

5.2 Sponsoring Business Unit or Engineering Organisation

5.2.1 General

The sponsoring business unit or engineering organisation is not a role defined in AS 7702 but is typically required from a business perspective as an enabler for compliance with AS 7702 as adapted by the particular evaluating RTO.

The sponsoring business unit or engineering organisation will typically be the one that will benefit most from the type approval. The sponsoring business unit or engineering organisation may be independent from the evaluating rail transport operator depending on commercial and organisational arrangements.

5.2.2 Sponsor

The sponsor will be an individual from the sponsoring business unit or engineering organisation.

The sponsor will be responsible for-

(a) Securing approval for the evaluating RTO to progress the type approval; and

(b) Coordinating with the lead engineer and introduction of the supplier where the need has arisen directly from the business.

If securing approval may require a business case, see Appendix 3: Guidelines for strategy and business case

5.3 Supplier

5.3.1 General

The supplier is responsible for providing all the information and evidence to support a substantial claim of compliance of their product against the requirements notified by the evaluating RTO.

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5.3.2 Supplier's Representative

The supplier's representative shall be a competent engineer who understands the technical requirements of the product being evaluated and can assess the product's specification against the evaluating RTO's requirements. The supplier's representative may be independent of the supplier but shall have access to the detailed technical information relating to the product specification, it's design, it's manufacture and testing.

The supplier's representative is responsible for:

(a) Populating the standards compliance register with the details of the reference evidence that demonstrates compliance against a requirement .

(b) Ensuring that for every claim of compliance that there is a referenced, available and verifiable piece of evidence that justifies that claim.

(c) Documenting and providing evidence for any counter argument to support a request for a derogation[1] .

(d) Ensuring that all supplied evidence documents in the product information pack meet the minimum requirements.

(e) Ensuring that for all evidence there is traceability between the version of product being assessed, its specification and reference standard against which compliance is being demonstrated.

(f) Ensuring that all test results are interpreted, documented and verified by a competent engineer.

5.4 Independent Safety Assessor

For a product offered by a supplier the supplier may have already engaged an independent safety assessor to assess part or all of the product being offered for approval.

If and independent safety report is offered with a product safety case, then the RTO shall assess the independence of the supplier from the safety assessor to decide if to accept the report as evidence.

6 Type Approval Process

The type approval process applies to any product provided for a signalling application that the RTO decides needs type approval. Each RTO will have their own criteria relating to the risk associated with safety and ongoing maintenance and operation. Appendix 2 provides further information on the general criteria that an RTO should consider when deciding if type approval is required.

The type approval process is outlined in the flow chart in appendix G of AS 7702, and has three key stages all of which are detailed in AS 7702:

(a) Submission –by the supplier to state the case for approval.

(b) Evaluation –by the evaluating RTO to assess the case for approval.

(c) Review – by the independent technical reviewer to approve the product.

[1] For example, an alternative technical solution to achieve the same outcome, compliance against an international standard with the same or more stringent requirements as noted in the local requirement.

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It is also outlined in more detail in this section, including the initial approach and request for type approval and in the flow chart in Appendix 1.

6.1 Process Overview

6.1.1 Type approval initial approach.

The process is initiated by a prompt from one of two sources:

(a) A supplier offering a new or improved product that may be of benefit to the RTO.

(b) A business need from a project, operational or maintenance requirement.

6.1.2 Type approval request

Once initiated a sponsor shall be identified for the product as defined in 6.3.1 and the lead engineer appointed, see 6.3.2, by the type approval authority.

The sponsor is then responsible for preparing, with the supplier representative, the type approval request. Refer to section 6.3.3.

The lead engineer shall then assess the type approval request against the RTO preliminary review criteria, see section 6.3.5.

If the outcome of the assessment of the type approval request is acceptance for type approval, then the lead engineer will prepare a type approval plan, see section 6.4.2.

6.1.3 Planning

The lead engineer will prepare the type approval plan, including the references for the type approval assessment requirements against which compliance will be judged. See section 6.4.2.

The type approval plan is then briefed to the RTO, business and supplier stakeholders at a kick off meeting. See section 6.4.3.

The lead engineer prepares the standards compliance register populated with the individual requirements This can be done in collaboration with the supplier's representative. 6.4.4 & 6.4.5.

6.1.4 Submission

The supplier's representative will then prepare the submission, populating the standards compliance register with the justifications of compliance, preparing the technical data in an evidence portfolio and the product information pack. See section 6.5.

The supplier provides the completed submission to the lead engineer for evaluation.

6.1.5 Evaluation

The lead engineer carries out the evaluation and requests any additional evidence as necessary to support any statement of compliance or non-compliance derogation. See section 6.6.

Once the lead engineer is satisfied that all the necessary evidence has been provided to satisfactorily conclude the evaluation then the lead engineer will prepare the type approval evaluation report. 6.6.6.

The type approval evaluation report will be reviewed by stakeholders as per the RTO peer review process requirements. See section 6.6.7

If the outcome of the type approval evaluation report review is that the product is acceptable for approval, then the lead engineer shall compile the product approval pack for approval by the type approval authority (as ITR). See section

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6.1.6 Approval

The type approval authority (as ITR) will carry out a final review of the product approval pack, sign the certificate and update the type approval register. See sections 6.7.1 & 6.7.10.

The type approval authority shall define any ongoing audits required for the supplier to maintain the type approval. See section 6.7.11.

6.2 Type approval - initial approach.

There are a number of ways that a type approval request is initialised, any can be classified as being prompted by one of the following:

(a) Business need.

(b) Direct approach from a supplier.

For any prompt for a type approval the initiation may be for a new product to the RTO, a change of product or change of application context. This code of practice applies to all cases.

Each RTO shall have a single point of contact for the initial approach for a type approval request from any source. The single point of contact shall be publicised and communicated for internal and external use.

There shall be a process for all requests to that single point of contact to be directed to the appropriate type approval authorities.

All approaches for type approval shall be logged by the RTO and tracked to their respective conclusion.

6.3 Type approval request

6.3.1 Sponsorship of type approval requests

The type approval authority shall seek sponsorship to progress a type approval, but if there is no appetite to sponsor a product then the type approval will not progress beyond the initial approach and the supplier will be informed.

The sponsor responsibilities are defined in section 5.2.2.

If the initial approach for type approval is from the business or engineering organisation, then the type approval authority will request for a sponsor from that business or engineering organisation.

If the initial approach is from a supplier, a general request for a sponsor will go to the potential businesses or engineering organisations that may want the product type approved.

6.3.2 Appointment of the lead engineer

The process for nomination and appointment of the lead engineer may be different for each RTO as dictated by the local commercial and business arrangements, the lead engineer might not be an employee of the RTO.

The appointment of the lead engineer shall be approved by the type approval authority.

The lead engineer shall be competent to carry out allocated responsibilities and where appropriate can be supported by a subject matter expert to whom some of the lead engineer responsibilities can be delegated.

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6.3.3 Preparing type approval request

Each RTO shall have its own type approval request process detailing the preliminary information they require to do the preliminary review.

It is the sponsor's responsibility to prepare the type approval request with the support of the supplier's representative.

The request shall include information aligned with the RTO preliminary review criteria for the lead engineer to review.

The information in the request will be assessed by the lead engineer to make a recommendation to the type approval authority on whether the product should be evaluated.

The preliminary review criteria will should consider:

(a) Existing product change notification.

(b) Business need.

(c) Likelihood that the product can be approved within a timeframe appropriate to the business need.

(d) Evidence of use in a similar application.

The type approval request is submitted by the sponsor to the lead engineer for assessment.

6.3.4 Request prompted by change

If the need for a type approval request has arisen from a notification of change the sponsor shall confirm if the product is still required before submitting a type approval request. If it is required, then the sponsor shall complete the appropriate type approval change form provided by the type approval authority, to be appended to the type approval request.

The type approval change form should contain at least the following information:

(a) The existing type approval for the product that is changed.

(b) The scope of the change.

(c) Detail of any relaxation of the full evaluation, approved by the type approval authority.

(d) Initial assessment on the impact of the change.

6.3.5 Request outcome

The lead engineer shall assess the type approval request and inform the sponsor of the outcome. If it is not approved, then the lead engineer shall inform the sponsor why.

If the sponsor still considers there is a need for the type approval they can, based on the feedback provided by the lead engineer prepare a new request with updated information. Otherwise the sponsor shall inform the supplier of the type approval request outcome.

6.4 Planning

6.4.1 General

If a type approval request is approved, then the plan and evaluation criteria shall be developed and communicated.

6.4.2 Type approval plan

The lead engineer shall prepare a type approval plan.

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The type approval plan is required to define the following for the particular type approval:

(a) Roles and responsibilities.
(b) Competency requirements for defined roles.
(c) Stakeholder identification and engagement.
(d) Independence requirements.
(e) Product requirements.
    (i) Existing procurement specifications.
    (ii) Requirements derived from engineering or maintenance specifications.
    (iii) Reference AS or other specifications.
    (iv) Requirements derived from hazard analysis.
(f) Scope of evaluation.
    (i) Full product, change to product or change of application.
    (ii) Relaxation in assessment of requirements (limited assessment).
(g) Intended application.
(h) Trial requirements.
(i) Define type approval deliverables.
    (i) Product information pack.
    (ii) Standards compliance register.
    (iii) Trial requirements.
    (iv) Trial report. See section **Error! Reference source not found.**.
    (v) Product approval pack.
    (vi) Type approval certificate

The lead engineer shall coordinate a review of the type approval plan with the relevant RTO and supplier's stakeholders before issue to assure that all interests have been properly represented in the plan.

6.4.3 Kick off meeting

It is the lead engineer's responsibility to arrange a kick off meeting and invite all stakeholders.

The purpose of the stakeholder meeting is to ensure that each understands their role and how the type approval will be managed.

Attendees shall include at least anyone with a defined role in the type approval plan

The following is an outline agenda for the kick off meeting:

(a) Introduction to the product.
(b) Stakeholder introductions and interest statements.
(c) Briefing of the type approval plan[2].

[2] Roles and responsibilities are of particular importance.

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(d) Non-compliance management – derogations.

The kick off meeting shall be minuted and retained for inclusion in the product approval pack.

6.4.4 Evaluation Criteria

The lead engineer shall identify the requirements list that will make up the evaluation criteria for inclusion in the standards compliance register.

If there is an existing standards compliance register, then this can be reviewed by the lead engineer to confirm it is valid.

The requirements shall be primarily derived from the standards identified in the type approval plan. If a compliance is required with a whole standard, then this can be listed a single requirement.

The evaluation criteria should support assessment that product meets the form, fit and functional requirements, including requirements for maintenance and ongoing operational performance. The requirements should also consider if any formal SIL requirements are to be defined.

The lead engineer shall carry out a risk assessment to assure that all safety requirements are identified and included in the standards compliance register. Where practical, existing risk controls shall be the preference for requirements in the standards compliance register, i.e. the RTO standard.

The requirements list shall be checked additionally to confirm they consider all evaluation criteria as listed in AS 7702 4.3, Appendix A and Appendix B.

6.4.5 Preparing the standards compliance register

The lead engineer shall prepare the standards compliance register; this may be in collaboration with the supplier's representative.

The lead engineer should consider the criticality of each requirement listed in the standards compliance register. It should be clear which requirements are preference requirements, not critical to the type approval.

The standards compliance register shall contain the requirements list for the product as identified by the analysis carried out as described in section 6.4.4; it will form the basis of the assessment record.

An example standards compliance register template is given in appendix D of AS 7702.

If an existing procurement specification is available with a related standards compliance register then that can be used, see Appendix 2.

The standards compliance register shall be approved by the ITR prior to being formally issued by the lead engineer to the supplier's representative, to populate.

6.4.6 Information provided to the supplier

The lead engineer shall provide the supplier's representative with the following to allow them to prepare their submission:

(a) The type approval plan.

(b) The template standards compliance register populated with the assessment requirements.

(c) Access to the RTO and any other restricted referenced standards.

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6.5 Submission

6.5.1 General

Preparation of the submission is the key responsibility of the supplier's representative.

6.5.2 Technical data – evidence portfolio

The supplier's representative shall prepare an evidence portfolio of all technical data and documentation referenced in the product information pack and the standards compliance register.

This portfolio shall be indexed such that it is easy for the lead engineer to trace a particular evidence item that supports a claim of compliance made in the standards compliance register

Each evidence item in the evidence portfolio shall be checked by the supplier's representative to confirm that it meets the minimum criteria, as defined in AS 7702 3.3.1

Any piece of evidence that does not meet the minimum criteria shall not be accepted and any claim referencing that evidence should be considered non-compliant.

Traceability between the design accepted at type approval and the supplied product is critical therefore all the supplier's representative shall ensure that all datasheets, designs, certificates of compliance trace back to the same verified product specification to assure that the product supplied is the product approved.

6.5.3 Product Information Pack

The supplier's representative shall prepare the product information pack. The contents of the product information pack are defined in AS 7702 3.3.3 and appendix C.

Essentially the product information pack is a report to support the evaluation of the product. It will provide any information that is relevant to that evaluation including reference to the documentation (evidence portfolio) that supports a justification to the lead engineer for acceptance of the compliance claim.

6.5.4 Completing the standards compliance register

The supplier shall make a statement of compliance against each requirement in the compliance register with a reference to the indexed evidence item(s) in the evidence portfolio that support that claim of compliance.

A requirement can only be claimed as compliant if it can be demonstrated it exactly matches the requirement and there is supporting evidence. Otherwise it shall be stated as non-compliant.

Unless a product was specifically designed to the RTO's requirements that 100% compliance against all requirements will not likely be claimed. The purpose of the evaluation is to understand the risk associated with the product in its intended application can be practically controlled.

Non-compliances can be accepted by acceptance of a risk assessed and justified derogation, see section 6.7.2.

Where the supplier has a justification and evidence that the non-compliance should be accepted as a derogation, with any necessary controls or conditions then this can be documented in "non-compliance details" and "non-compliance controls" of the register.

Types of justifications which should be considered control for the non-compliance may include:

(a) Compliance demonstrated against an equivalent standard.

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(b) Alternative design mitigation.

(c) Function or protection can be provided external to the product.

(d) Alternative risk control.

(e) Requirement not applicable to the design.

(f) Field trials proposed to gather further evidence.

The supplier's representative shall sign the standards compliance register as required by AS 7702 3.3.2.6a.

The signature is to confirm that the supplier's representative is competent to make the claims justified in the standards compliance register and that it is a true and accurate representation of the supplier's product compliance.

6.5.5 Submission documents

The supplier's submission documents shall be sent to the lead engineer.

The supplier's submission documents shall include the following information from the supplier as specified in AS 7702 3.3:

(a) Technical data (evidence portfolio) – AS 7702 3.3.1 & Appendix B.

(b) Product information pack - AS 7702 3.3.2 & Appendix B.

(c) Completed standards compliance register - AS 7702 3.3.3 & Appendix C.

The evaluation requires a minimum of two things to be established for a recommendation for approval to be made, that the product -

(a) design will meet the safety and functional requirements.

(b) is assured to continue to be manufactured as designed.

The supplier shall have a quality management system that covers design, manufacture and test of the product, evidence of that shall be included in the submission documentation, see AS 7702 3.3.1.5.

The quality management system should be accredited, however the RTO can at their discretion to accept a supplier's quality management system based on audit of that quality management system.

Where a supplier is not the designer or not the manufacturer they shall be able to demonstrate that the designer and manufacturer has a quality management system to the satisfaction of the RTO as well as one that covers their own contribution to the assurance of the product that shall also be supplied to the RTO.

6.6 Evaluation

6.6.1 Preliminary evaluation

The lead engineer shall review the received submission documentation.

The lead engineer shall carry out some preliminary checks before completing the detailed - assessment. The lead engineer shall check -

(a) For evidence of quality management system(s) for design, manufacture and test;

(b) That all evidence in the evidence portfolio meets the minimum requirements as specified in AS 7702 3.3.1; and

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(c) That the supplier's representative is a competent engineer capable of assessing compliance of the product.

Any deficiencies shall be notified immediately to the supplier's representative to action as appropriate.

6.6.2 Detailed evaluation

The lead engineer shall review each claim of compliance to evaluate the supplier's assessment and confirm agreement or not. Any compliance claims not agreed will be marked as non-compliant.

The lead engineer shall make reference to the requirements of AS 7702 4.5.1 and 4.5.2 when making their evaluation.

The lead engineer shall review each assessment of non-compliance to consider if further evidence is required or that the non-compliance can be accepted as a derogation and on what conditions.

The lead engineer shall specifically check for any safety related application conditions defined by the supplier. The safety related application conditions shall be evaluated to confirm that they are practical for the RTO to comply with in the intended application(s).

6.6.3 Request for additional evidence

Where the lead engineer requires further evidence a request for information (RFI) will be raised and sent to the supplier's representative.

Any RFI raised shall make specific reference to the particular requirement in the standards compliance register and evidence item to which it relates to avoid confusion as to the purpose of the request.

If there is a significant number of RFI's in relation to a submission, then the lead engineer and the supplier's representative shall discuss in person the additional evidence. The discussion is to ensure that the reason for the additional evidence is understood and discuss any potentially acceptable counter evidence for derogation approvals.

6.6.4 Lack of evidence

If it is identified by the lead engineer and the supplier's representative that a product might be compliant with a particular requirement but no suitable and sufficient evidence exists, then the lead engineer has two options.

The options are to secure evidence of compliance or for acceptance of a derogation:

(a) Instruct the supplier to carry out the necessary technical evaluations.

(b) Define a controlled trial.

If the trial option is selected, then actions shall be identified relevant to the trial environment to control any assessed risk associated with the product not being compliant to that requirement.

Where evidence from a trial is required then the lead engineer shall define with the supplier's representative a trial implementation plan see section 7.

6.6.5 Concluding the evaluation

The evaluation will be concluded once all individual requirements stated in the compliance register have been accepted as:

(a) Compliant.

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(b) Compliant by alternate demonstration.

(c) Not yet compliant to be assessed by trial, interim controls defined.

(d) Not yet compliant, non-safety critical, post-trial close out.

(e) Non-compliance accepted with defined controls – derogation.

Accepted controls will be the details of any conditions noted with the type approval certificate.

Depending on the experience and demonstrated performance of the product in a rail environment, as considered at the planning stage, the product may be subject to trial as part of the RTO evaluation.

6.6.6 Type approval evaluation report

The lead engineer shall prepare the type approval evaluation report for review by the stakeholders and type approval authority (independent technical reviewer).

The type approval evaluation report shall document the following

(a) Introduction

(b) Scope

(c) References

(d) Supplied evidence index

(e) Assessment overview

(f) Summary of interim approval conditions (where there is a trial)

(g) Summary of approval conditions

(h) Summary of outstanding evidence (to be supplied post trial)

(i) Summary of RFI

(j) Conclusion

(k) Recommendation

(l) Supplementary information (reference storage location)

(i) Evidence portfolio

(ii) Product information pack

(iii) RFIs

(iv) Derogations (from which condition are derived)

(v) Stakeholders questions and answers

(vi) Minutes and correspondence

The detail in the report shall be in sufficient detail that the stakeholders should be able to review without a need to refer to the supplementary information, able to take at face value that the supporting evidence has been provided and is satisfactory.

The lead engineer shall make a recommendation for full, provisional, restricted or no type approval. The lead engineer shall endorse the standards compliance register with a signature. That signature will be to confirm responsibility and competence for the review of the evidence.

The recommendation for approval shall be one of the types as defined in AS 7702 6.1.3:

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(a) Full

(b) Provisional

(c) Restricted

6.6.7 Stakeholder review

The last step in the evaluation is the stakeholder review.

The lead engineer shall provide a copy of the type approval evaluation report to the stakeholders and coordinate a stakeholder review of the report.

If the stakeholders are satisfied with the report and recommendation, then they shall provide a response confirming that is the case to the lead engineer.

If a stakeholder has a question, then it shall be directed to the lead engineer who will retain a record of each question and the associated response for inclusion in the product approval pack, the questions will be supplementary to the report.

The lead engineer shall be responsible for answering all stakeholder questions.

If a question raises a concern that requires the lead engineer to return to the supplier's representative for further information, then that shall be dealt with through the RFI process as was used in the evaluation.

Once the questions have all been responded to, the stakeholders have no more questions and the recommendation is accepted in principle then the lead engineer shall prepare the product approval pack as defined in AS 7702 4.4.1, excepting the draft type approval certificate which will be prepared after the independent review.

The product approval pack shall additionally contain:

(a) The type approval change form (if applicable).

(b) The type approval request.

(c) All Requests for information (RFI).

(d) Correspondence and meeting minutes.

6.7 Approval

6.7.1 Independent Technical Review

The review is defined in AS 7702 5.

The type approval authority or delegated representative is expected to take on the role of the independent technical reviewer (ITR) as specified in AS 7702 2.4. The ITR has the authority to approve or not the type approval of a product based on the information in the type approval evaluation report, the reviewed standards compliance register and associated supporting documentation.

The ITR appointment shall meet the criteria as specified in 2.4.1

The review should consider at least the following:

(a) The acceptability of the supplier's quality management system.

(b) Subordinate quality management if the supplier is not the design or the manufacturer.

(c) The competence of the supplier's representative to carry out the supplier evaluation.

(d) The competence of the lead engineer to carry out the evaluations.

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(e) Detailed review of all non-compliant items to agree controls and approve any proposed derogations.

(f) Review of acceptability of any not yet compliant items for trial evaluation or post trial completion.

(g) Overall adequacy and detail of the type approval evaluation report.

The ITR shall provide written feedback to the lead engineer with any queries documented individually including any further requests for information from the supplier's representative.

The lead engineer is responsible for responding to each query to the satisfaction of the ITR, if necessary then the lead engineer will raise a new RFI to the supplier 's representative to allow an appropriate response to the ITR.

Response to the ITR queries will be fully documented as a supplement to the type approval evaluation report and included in the product approval pack to provide full documentation of the approval.

6.7.2 Derogation acceptance

The ITR shall review each derogation to decide if it can be approved.

The ITR acceptance of a derogation should consider the following factors:

(a) It has been demonstrated by the supplier's representative that it is not reasonably practicable to comply with the stated requirement.

(b) It has been demonstrated by the supplier's representative that the risk associated by the derogation is tolerable.

(c) it has been demonstrated by the supplier's representative that all reasonably practicable steps (including additional control measures, as necessary) have been taken in order to limit the risk associated with the non-compliance.

If the ITR has any questions, then these shall be directed to the lead engineer. The questions and responses will be logged as they were in the stakeholder review section 6.6.7

6.7.3 Provisional Approval

If the approval by the ITR is provisional then it is only interim and the product shall be subject to trials, see 7, before full approval can be considered.

The provisional approval will be limited to the duration of the trial plus an allowance for review and evaluation of that trial. Any extension of a provisional approval shall be approved and documented in the product approval pack by the type approval authority.

6.7.4 Restricted Approval

If the approval by the ITR is restricted then the certificate shall include details of that restriction, the location or the specific application.

6.7.5 Certification

Once the ITR is satisfied with the documentation and all non-compliances and derogations have been addressed, appropriate to the class of approval being considered for the product, then the lead engineer can draft the type approval certificate with reference to any general or specific type approval conditions.

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6.7.6 Standard condition

General conditions are obligations on all suppliers that provide product to the RTO as defined in AS 7702 2.3 and any other RTO standard requirements.

The following is a list of standard conditions that can be referenced on any RTO type approval certificate.

Type approval granted subject to the following standard conditions.

General conditions:

(a) Alterations to the certificate made other than the by the type approval authority will invalidate the certificate.

(b) Failure to abide by the conditions of approval may invalidate the approval.

Supplier obligations:

(c) Notify the RTO of any-

(i) Known safety issues as soon as possible but no later than within 24 hours;

(ii) Performance issues with 72 hours;

(iii) Any known reliability issues within 72 hours;

(iv) Significant changes to the manufacturing process;

(v) Change to the product's quality assurance accreditation;

(vi) Intended change to the design;

(vii) Change of name or ownership of the supplier;

(viii) Discontinuation of product or support 12 months in advance, if known or as soon as possible if outside of the supplier's control;

(ix) Provide up to date documentation for operation, maintenance, installation and training;

(x) Warrant the manufacture and performance of their product for an agreed timeframe, which will be at least 12 months;

(xi) Change to the components, design or manufacturing methods of the product shall be risk assessed considering the rail application context and any risks managed to protect the safety and performance of the product;

(d) Allow the RTO to audit their quality management system, with due notice.

Conditions of use

(e) Those who use the product or reference the product in design or specifications shall:

(i) Comply with all the conditions of approval and seek guidance in interpretation from the type approval authority when a condition is not clear.

(ii) Verify that the version of the product they are referencing or using is the same as that referenced in the approval certificate.

(iii) If any change in configuration is identified by the user, notify the RTO of that change.

(iv) Report any safety, performance or reliability issues to the type approval authority.

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(v) Operate, maintain and service the product in accordance with the supplier's safety related application conditions and any product manual requirements.

(vi) Only send the product for repair to the original equipment manufacturer.

(vii) Acknowledge that product acceptance does not substitute or reduce the need for competent engineering.

(viii) Accept that the approval by the RTO is limited to applications for that RTO only.

(ix) Approval does not infer any preference of one supplier over another, only that the product has been evaluated and assessed as acceptable for use as per the defined scope.

6.7.7 Specific conditions

Specific conditions will be related to the particular evaluation and those conditions will be associated with noted non-compliances, these may be associated with:

(a) Design.

(b) Test.

(c) Maintenance.

(d) Application type.

(e) Application environment.

(f) Procurement, storage and handling.

6.7.8 Documenting conditions

The type approval certificate shall be compliant with the requirements defined in AS 7702 6.2, and for provisional approval include additional information as in AS 7702 6.3 and for restricted approval include the information defined in AS 7702 6.4. A sample certificate is provided in AS 7702 Appendix E.

Each certificate shall include or be supplemented by conditions.

Standard conditions can be summarised by referencing section 6.7.6 of this standard.

Specific conditions shall be listed individually.

6.7.9 Product approval pack

Supporting every certificate as per the requirements of this code of practice will be a product approval pack.

The product approval pack will contain the following information:

(a) All information as defined in AS 7702 4.4.1.

And where applicable:

(b) Type approval change form.

(c) Archive copies of earlier type approvals of a changed product.

(d) Extension of provisional approval.

6.7.10 Type approval register

To maintain a type approval register is a requirement of AS 7702 8.3.

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If a product has been approved or not is essential information for anyone involved in design and maintenance, knowing the approval status allows them to make an informed decision on the use of a proposed product.

The design or maintenance engineer needs to be able assess the benefit of gaining type approval from a technical delivery and operational perspective or decide whether an existing approved product will be acceptable in the design.

Each product that has a type approval certificate issued shall be recorded in a type approval register by the type approval authority.

The product shall be registered with the unique certificate number, requirements for certificate are given in section 6.7.5.

The detail recorded in the register by the type approval authority shall include sufficient details to identify the product type, supplier and the location of the type approval certificate with its conditions of approval.

Ideally the register will be available electronically with a link to the certificate and conditions of approval, accessible to anyone both internal and external to the RTO.

6.7.11 Audit

Once a type approval is granted as a full or restricted type approval then no review of the type approval is required unless the product has a notifiable change as defined in 8. Notification of a change is reliant on the supplier fulfilling the responsibilities outline in AS 7702 2.3 or notification by a user.

To further ensure that the product design remains as per the type approval, that the quality of manufacture to that design remains assured and that all changes are notified it advisable for the type approval authority to consider planning and conducting audits of those suppliers.

Audit planning should be considered in the context of the known integrity of the supplier and the criticality of the products they supply.

The known integrity of the supplier shall be established by a range of criteria likely to include the following:

(a) In service product history with the evaluating RTO.

(b) References from other RTO's that have approved the supplier and the product.

(c) Feedback from maintenance and operations on performance of the product.

(d) Other interactions with the supplier directly or indirectly.

New suppliers with no known in service history for railways should be considered as high risk until they have a proven history.

It is recommended that RTO's make their type approval documentation available this should include their audit documentation so that an RTO can accept another RTO's audit in lieu of carrying out one of their own. This will limit the effort by the RTO and the number of times that a supplier shall be audited by a third party.

IRIS (future reference ISO/TS 22163) accreditation relative to the product being supplied can be considered acceptable audit evidence.

The output from the audit will be an audit report documenting any observations and improvements.

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Any critical non-compliances that have the potential to result in withdrawal of type approval will be dealt with as outline in section 11.

7 Trials

7.1 Trial requirements

Requirements for trials are defined in AS 7702 4.6

7.2 Trial identified at planning stage

If there is no suitable in service reference, then the lead engineer can identify a trial in the planning stage of an evaluation. If tin service evidence is limited, then a trial should be recommended at the planning stage.

7.3 Trial due to insufficient evidence

It is possible however that during the evaluation that suitable and sufficient verified evidence is not readily available for a range of reasons, particularly with products that have not been specifically designed for rail applications then the evaluation may highlight that the only practical method of assessing compliance is to carry out a field trial.

7.4 Trial risk management

Field trials pose a risk as a not yet fully assessed product is being installed into an operating environment that may have direct or indirect impact on safety. The lead engineer shall ensure those risks are identified, assessed and appropriate acceptable controls defined to manage those risks within acceptable limits for the purposes of the trial.

7.5 Trial implementation plan

Any trial shall be carefully defined in a trial implementation plan.

The trial implementation plan will document the following:

(a) Purpose of the trial.

(b) Roles and responsibilities of stakeholders.

(c) Communication with stakeholders.

(d) Risk assessment for the trial.

(e) Additional maintenance or inspection tasks.

(f) Additional remote monitoring.

(g) Trial evaluation criteria.

(h) Trial outputs:

  (i) Trial results.

  (ii) Trial report.

  (iii) Updated type approval evaluation report.

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7.6 Responsibility for running a trial

The lead engineer shall decide if the RTO or the supplier shall be responsible for the implementation, review of the trial results and the production of the trial report.

7.7 Trial outputs

The trial will essentially provide additional evidence for the evidence portfolio (technical data), and following the trial each requirement where the outcome was “Not yet compliant to be assessed by trial, interim accepted controls” shall be reviewed to confirm if the outcome of the trial was acceptable or not.

The trial report and related results should be considered additional evidence for the purposes of the type approval evaluation and added to the technical data in the evidence portfolio.

The lead engineer will then carry out a re-evaluation following the same process as defined in 6.6 but using the initial evaluation as the basis, taking into account the additional trial evidence.

The lead engineer shall also ensure that all requirements that were identified as post trial close out items are also completed before a recommendation for full type approval can be considered.

8 Revision to existing type approvals

8.1 Notification of Change

8.1.1 Supplier notified change

Included in the general conditions of type approval in section 6.7.6 is the requirement for the supplier to notify an RTO of a change this also generally specified in section 2.3 of AS 7702

This section provides further guidance on what is a notifiable change.

8.1.2 Change notified by others

A change may also be notified to the type approval authority from the users of the product, where the supplier has not yet notified the RTO of that change.

8.1.3 Notifiable change

If a supplier is in any doubt as to whether a change is notifiable or not, then they shall notify the RTO anyway.

As per the general type approval conditions the supplier shall have a management of change process that includes risk management.

A notifiable change is any change to -

(a) The principle of the product design;

(b) A different type of component (for example spring terminal to screw terminal);

(c) The form, fit or function of the product;

(d) Specialist tools associated with the product (hardware or software);

(e) Any of the associated specifications;

(f) Any of the safety related application conditions;

(g) Any of the product manuals;

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(h) A lesser safety or performance of the product; or

(i) Firmware or software.

8.1.4 Non-notifiable change

A change that is not notifiable as defined in section 8.1.2 is to be assessed as per the supplier's quality management system to assure that no degradation in the safety or performance of the product is introduced as a result of the change. The assessment should consider the rail application context.

8.2 Communication of a change

8.2.1 Engineering Notice

When a notification of change is received the type approval authority can consider if it necessary to ensure that users of the product are aware that the change has taken place and that the changed product is not yet approved.

If the type approval authority thinks it necessary, an engineering notice shall be issued advising users that the product has a change.

The engineering notification shall define what checks to put in place to assure the version in use is an approved version.

8.3 Review of the notification of change

8.3.1 Review of the change

The type approval authority will review each notification of change and consider any risk associated with that change and whether a type approval evaluation of that change is required or not.

A type approval evaluation will not be required for one of two reasons:

(a) Type approval authority has established there is no requirement for the changed product, no sponsor.

(b) Type approval authority has assessed that the change is non-material and low risk.

8.3.2 Evaluation of the change

If a type approval evaluation is required, then the evaluation will follow the process defined in this code of practice in section 6.

8.3.3 Limited scope evaluation of the change

In the case of a change the type approval authority can approve a relaxation to the evaluation process by limiting the scope of the evaluation to the requirements impacted by the change only.

The assessment of the change and approval for limited scope shall be documented on at type approval change form.

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8.4 Change records

8.4.1 Type approval change form

An RTO shall have a defined type approval change form on which the type approval authority can record their assessment of the change and a justification for no review or limited review, full review or withdrawal associated with a change notification.

The type approval change form shall also have space for the sponsor's review for use if the type approval authority considers and evaluation is required. The type approval change form shall be included by the sponsor with the type approval request, see section 6.3.4.

8.4.2 No evaluation required

Where the type approval authority assesses the existing approval can be maintained, without further evaluation, the completed type approval evaluation form signed by the type approval authority will be added to the type approval pack as a record of that review and assessment.

8.4.3 Evaluation required

Where an evaluation is required, as for any other type approval evaluation a sponsor and lead engineer shall be appointed to make and assess a formal type approval request, see section 6.3.

8.5 Scope of Evaluation

8.5.1 Limited scope

If the type approval authority approves a limited scope evaluation, the lead engineer shall review the standards compliance register to identify which requirements are impacted by the change and only evidence associated with those requirements need be updated in the evidence portfolio and reassessed. To be approved by the ITR. All unaffected requirements will be noted in the updated compliance register as "no change". No further evidence is required to demonstrate each of these requirements.

8.5.2 No existing standards compliance register

If a standards compliance register does not yet exist then this shall be created by the lead engineer as for any other type approval, see section 6.4 for all requirements but with the requirements that remain unchanged marked as "no change".

8.5.3 Documentation

The detail of the reduced evaluation will be documented in a type approval plan. The same level of documentation will be required as for a full approval but based on the original approval documentation as an updates to documents with all original versions retained as part of the product approval pack.

9 Grandfather rights

9.1 Definition of grandfather rights

9.1.1 General

6.5 of AS 7702 covers grandfather rights.

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9.1.2 Existing products in service

Any product that is already in operational use in the infrastructure managed by an RTO can be considered approved by grandfather rights, for that particular location and application.

It is up to the individual RTO to decide if a product approved by grandfather rights can be considered type approved for use in new or altered infrastructure where the application context is the same.

9.1.3 Threshold date

The RTO shall define a threshold date for any product to be considered as type approved by grandfather rights. All products after that date even if they are in service shall have undergone a formal type approval review.

9.1.4 Type approval register

It is recommended that the RTO includes all products approved by grandfather rights in their type approval register.

9.2 Revision to grandfather rights

9.2.1 Change to grandfather rights approval

If the product is changed or the application context is changed for a product that is approved for use by grandfather rights, then it shall be formally approved as per the requirements of this code of practice.

9.2.2 Grandfather rights standards compliance register

As with any other change the type approval authority can agree a limited scope of review as defined in section 8.

As with any other evaluation the requirements shall be defined by the lead engineer. The standards compliance register will document in detail the requirements applicable to the change. Other requirements can be recorded on block providing the the ITR approves the justification for those block requirements.

In recording the assessment in the standards compliance register, instead of noting “no change” against unchanged requirements the lead engineer shall record “compliant by grandfather rights”

10 Use of cross acceptance

10.1 Cross acceptance definition

Cross acceptance is recognised in AS 7702 in section 4.7 and guidance is provided. Cross acceptance is where there an opportunity for a substantial reuse of documentation from a type approval for another RTO.

10.2 Factors for consideration

For cross acceptance to be considered the RTO shall be able to secure a copy of the type approval requirements and type approval evaluation report or safety case for the reference type approval.

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The process for dealing with cross acceptance shall be similar to the process for dealing with a change as defined in 8, in so much as it is the differences that need to be identified.

In the case of cross acceptance, the changes will not be the product but the environment and application context.

The differences between the approval context for the product offered for cross acceptance should be considered and documented by the lead engineer. The lead engineer shall identify any RTO requirements that are different or additional when compared to the cross acceptance documented requirements.

10.3 Cross acceptance standards compliance register

The standards compliance register shall be prepared by the lead engineer as for any other type approval however the requirements that are the same as the reference cross acceptance approval will be noted as “compliant by cross acceptance”. For the remaining requirements the supplier’s representative shall provide the product information pack and complete the standards compliance register for just the remaining unverified requirements.

The type approval evaluation will then proceed as for any other type approval.

10.4 Further guidance

Cross acceptance is included in EN50129 and guidance is provided in (CLC/TR 50506-1:2007).

11 Withdrawal of type approval

11.1 Decision for withdrawal

Withdrawal of type approval is on the advice of the type approval authority acting as the independent reviewer or maintaining the type approvals.

The criteria for withdrawal of type approval is given in AS 7702 section 7.

11.2 Notify supplier of intention

Intention to withdraw approval shall be notified to the supplier by the type approval authority as soon as is practicable to allow them to discuss the reason’s any possible actions to retain the type approval.

The type approval authority shall ensure that the supplier is provided with details of any allegations of faults relating to their products so that the supplier can support the investigation.

11.3 Alleged deficiencies

Where any product deficiencies are identified as a result of an investigation, the type approval authority shall work with the supplier to agree actions to allow them to resolve the problem to avoid an unjustified withdrawal of a type approval.

11.4 Confidentiality

Appropriate confidentiality of the investigation shall be respected by the type approval authority and any RTO representatives involved in an investigation, notwithstanding the responsibility to notify other RTOs of any serious safety concerns.

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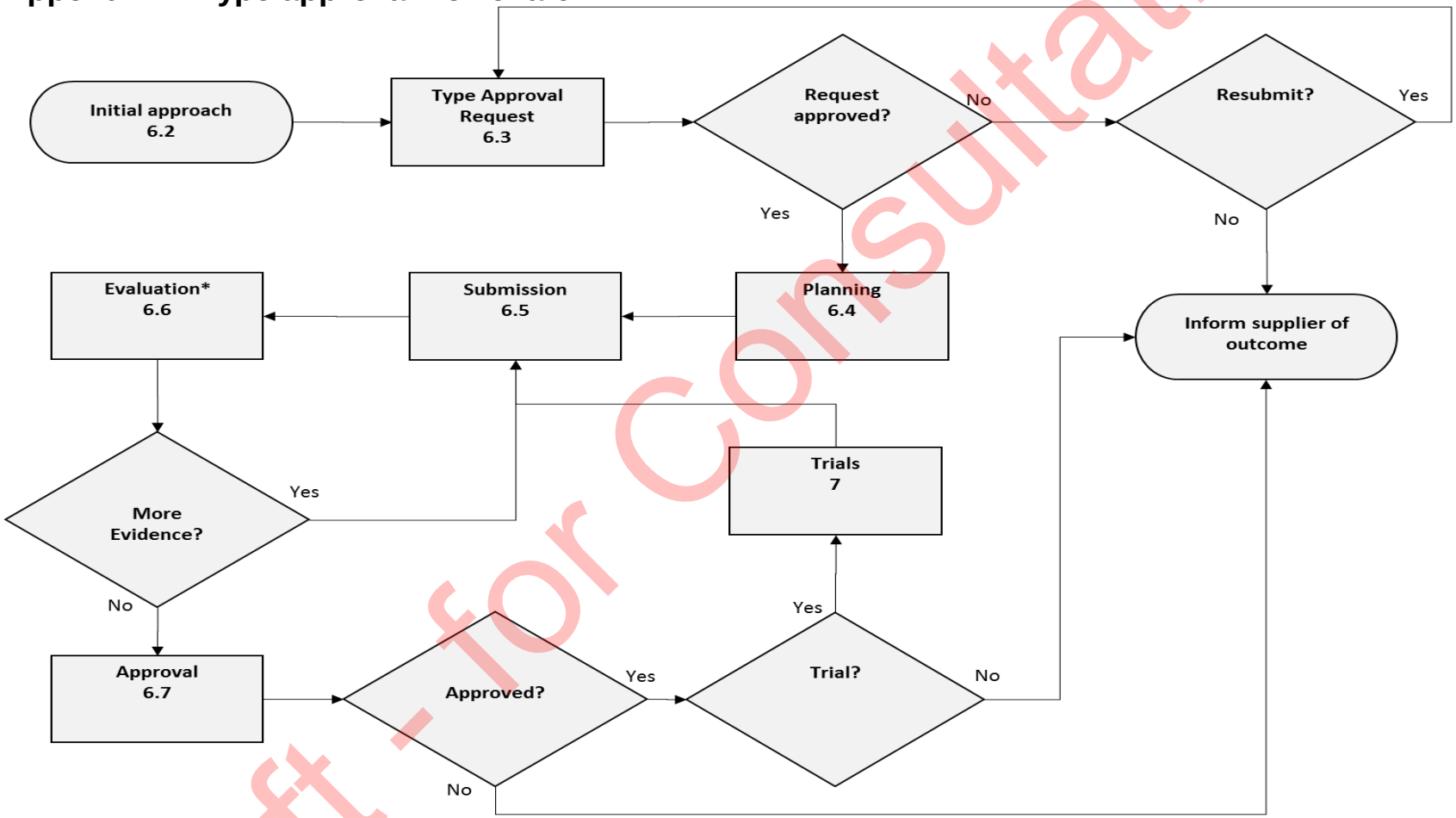
Appendix 1: Type approval flowchart



*Limited scope evaluation may be approved.

See section 8 revision of existing, section 9 cross acceptance, section 10 grandfather rights.

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Appendix 2: Type approval items

An RTO may nominate any products as dictated by their assessed business risk, Safety Management System and Asset Management Strategy for type approval.

The primary consideration will be safety impact and whether an existing standard reference is already in existence is entirely appropriate to the product and its use in the RTO context.

It is recommended that for items that are known to need type approval and where the functional requirements of products, operating environment and interface requirements of the following items are typically well understood within the RTO's context that the RTO should have a procurement specification that can be used as the single reference for the type approval standards compliance register, ideally the standards compliance register will be part of the standard and ready for issue to a supplier.

A fully developed procurement specification provides consistency in assessment of different product types and makes the type approval process more efficient as it can be started immediately rather than being delayed by the research activity to identify requirements in a range of RTO specifications and other standards and confirmed to meet the asset management strategy and safety management system requirements, this should be used as a basis on which to develop the standard to support the objective to allow substantial cross acceptance between RTO's.

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Appendix 3: Guidelines for strategy and business case

When a sponsor requires a type approval then a justification may need to be prepared.

The justification will be on immediate or future business need or advantage.

The following are justifications for consideration when a sponsor is preparing a business justification for a type approval submission:

(a) Product is manufactured under license by a different manufacturer for an existing approved design.

(b) Improved functionality offered compared to other similar products.

(c) Current product used for application has notified discontinuation of manufacture.

(d) Support for current product has been discontinued.

(e) Spares for existing product are long lead time or costly.

(f) Existing product has changed and old version no longer manufactured.

(g) New product provides a technical advantage that will increase operational reliability.

(h) Significantly more reliable product which provides an improved whole of life cost.

(i) Product provides significant cost benefit with minor changes to standard design.

(j) Reduced design cost due to simpler configuration, may be dependent on long term asset renewal strategy.

(k) Product is the same as an existing product but provides competition and diversity in the supply chain

In all cases the cost of the evaluation should be factored in to any cost benefit analysis of particular importance if there is not a long term strategy to use a particular product.

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