

# ADMIN 4.4

## Product Validation

- **Version 6**



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# DOCUMENT CONTROL

## Identification

Document Title	Number	Version	Date
Procedure for Independent Validation	ADMIN 4.4	1	20/07/2007
Procedure for Independent Validation	ADMIN 4.4	2	14/06/2009
Procedure for Independent Validation	ADMIN 4.4	3	03/05/2010
Procedure for Independent Validation	ADMIN 4.4	4	23/09/2010
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## Document History

Publication Version	Effective Date	Page(s) Affected	Reason
1	20/07/2007	All	Document Creation
2	14/06/2009	All	QMS System update of document
3	03/05/2010	All	Update of entire document following review
4	23/09/2010	All	Review and update
5	28/08/2012	All	Review and update
6	18/11/2014	All	Review update and include workshop

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# Product Validation

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## 1 Purpose

This procedure applies to the Validation Stage of a Product Development Process.

The purpose of validation is to provide an independent and critical review of a draft RISSB Product with the aim to identify deficiencies and the solutions.

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## 2 References

All Terms, abbreviations and acronyms used in this document are defined in the *RISSB Glossary*

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## 3 Process

This document sets out the process by which a RISSB draft product is validated before it progresses to the approval stage.

### 3.1 Overview

A Draft of a RISSB Product is subject to an independent validation after it has been accepted by the SC (on recommendation of the DG).

### 3.2 Process

#### 3.2.1 Awarding the Contract

RISSB Project Managers are to identify, through a Request for Services (RFS), an independent person/party to validate a draft RISSB standard, code of practice and rule. This person/party may be chosen at the same time the author of the product is chosen or at a later date and shall be advised in writing of the engagement through a 'letter of offer'. Other bidders for the validating the draft product are to be advised by email or letter that they were unsuccessful for the validation contract.

The letter of offer is to advice, amongst other matters, when validation is anticipated.

It is vital that the Validator be independent of the product's authoring process. Any connection will void the validation process.

Guidance material such as guidelines and Handbooks are validated by the RISSB Standing Committee and not by an independent person/party. The reason for this is twofold. First, guidance material is not enforceable. Second, the cost associated with independently validating a product is expensive.

But guidance material still needs to be validated to provide the RISSB Board with assurances that the author has met his/her remit. Validation of guidance material is carried out by the relevant RISSB Development Group after which it is passed directly to the appropriate RISSB Standing Committee for approval before the RISSB Board approves it for issue and use by the Industry.

### 3.2.2 Independent Validation

The Validator is to review the Draft RISSB Product performing the following tasks:

1. If the product is a standard, check that all the foreseeable hazards for the Major Elements have been identified. Otherwise check that the scope of the product is sufficiently addressed by the content.
2. Check that the relevant hazards have a control. This task entails checking that the hazards that should have a control do have a control in the standards.
3. Indicate whether or not the content within the product (including controls if it is a standard) is considered to be good practice. This task entails checking that the content is at least equivalent to recognised standards, Codes, Rules or controls used domestically and internationally.

*Note that “good practice” is not “best practice”.*

4. Indicate whether or not the content in the product is considered to be appropriate for the Australian rail industry on a national basis. The PM may raise specific issues/content to be considered in the validation - these typically arise from concerns raised by the industry.
5. Provide a recommended solution for any deficiencies identified in the above four (4) tasks. This task requires that a Validator state what they believe should be written in the Standard, Code of Practice or Rule. Where the answer is unknown the validator should provide a means to determine it.
6. Attend a RISSB workshop where the Validated final draft product is tested by interested industry stakeholders, DG members and on occasion invited Risk & Human Factor experts)

Validation does not involve:

- checking or commenting on style, format or structure;
- reviewing the development process;
- performing an independent Quality Assurance audit, (apart from that described in tasks 1 to 4 above);
- creating wholesale suggested rewording; and
- having a general discussion about an issue without concluding with a clear and unambiguous statement.

The standards are to be developed and published in a spreadsheet format, which will assist the validation process as each requirement is uniquely identified and contained within separate rows.

The focus of the validation of standards is on the controls prescribed in the standards, i.e. the mandatory (MAN) and recommended (REC) requirements, whilst the focus of validation of Codes of Practice and rules is on the content more broadly. The report should target those requirements that are missing, incorrect/wrong, apply an inappropriate control/content or are not considered good practice.

### 3.2.3 Standing Committee Validation

The PM is to provide the Standing Committee with a final draft of the Guideline/handbook etc. The Standing Committee members will critically review the document and advise the PM where changes are necessary. The PM adjusts the draft document and submits it for final approval through the approval process.

## 3.3 Validation Report

The Validator performs a review of the Industry Draft of the Standard and provides comments in a draft validation report. It should be noted that there is no recommended layout for validation reports - this is left to the discretion of the Validator. However, the following details should be observed:

- Reports shall be supplied in electronic format and written in 'plain' English.
- Reports shall use the metric system for units of measurement.
- The Validator supplies specific clause comments in the standard spreadsheet (for standards only).

Following the Validator's review, the PM examines the Validator's draft report, which is then forwarded to the DG and SC for their review. On completion the PM forwards the DG and SC comments on the report back to the Validator for him/her to consider when finalizing the Validation report.

Once the PM receives the Validator's final report, the PM issues the report and any associated directions to the author. The author is to revise the product, taking into consideration the validators recommendations, and to document their response to the recommendations. The revised Draft Product then enters the Product Approval Stage. If the Validator's report is not accepted by the PM, the Validator must re-examine the Product.

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## 4 Record Requirements

The following records are retained as evidence of compliance to this procedure:

- Sharepoint Records