



# BEST PRACTICE: AU v3.2 VALIDATION – WARNINGS.XML

# 1 Revision History

To ensure alignment with the latest regulatory requirements, Ennov follows a structured approach when Health Authorities release new specifications. For specifications with limited technical impact, Ennov’s InSight Business Consulting Team conducts a thorough review and updates our Best Practice documentation.

<b>Software Version</b>	<b>Release/ Revision Date</b>	<b>Summary of Change(s)</b>
v5.1.19	7-July-2025	Initial Authoring

## 2 Document Purpose & Scope

Ennov has introduced support for Australia eCTD Validation Specification version 3.2 in the Ennov InSight Validator version 5.1.19. This specification includes a new feature, warnings.xml, which is designed to allow the user to provide justifications to warnings in validation in a distinct file contained within the sequence folder. This best practice is designed to aid users in creating this file using Ennov InSight Validator.

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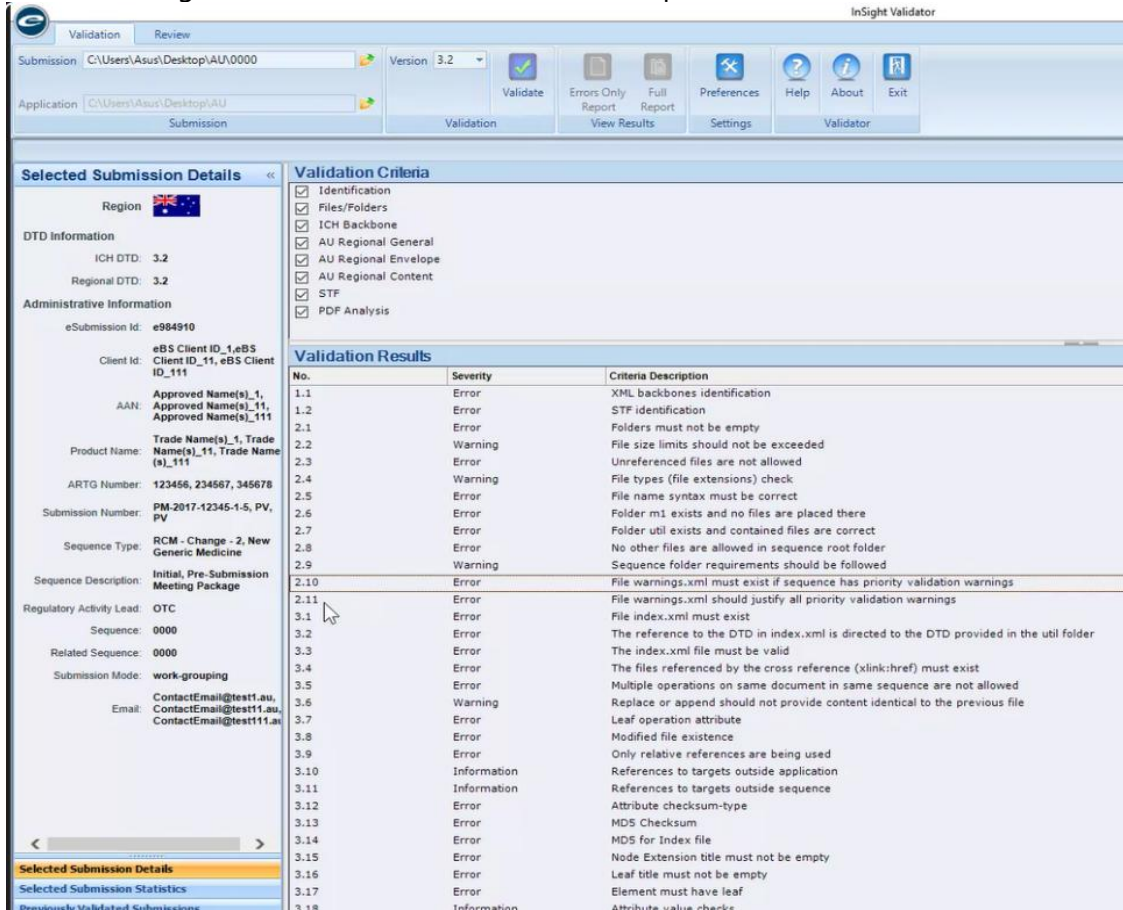
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## 4 Best Practice AU v3.2 Validation

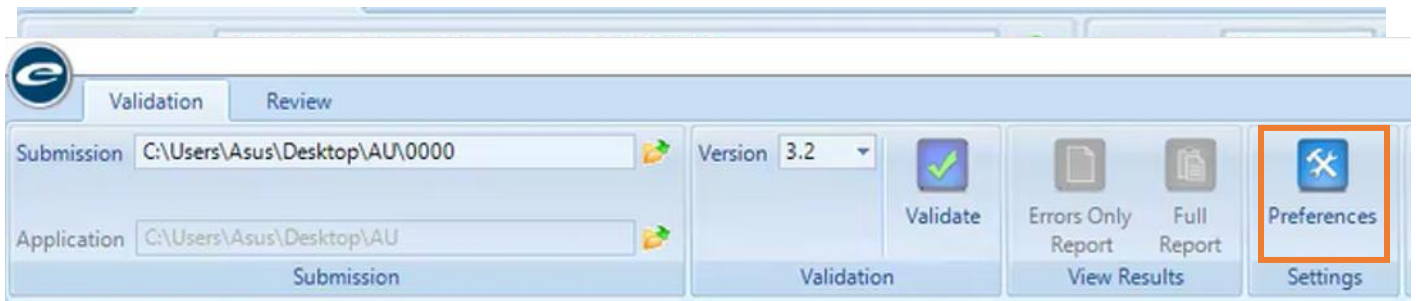
Users should follow the steps to create a warnings.xml file from InSight Validator.

### 4.1 Creating the Warnings.xml

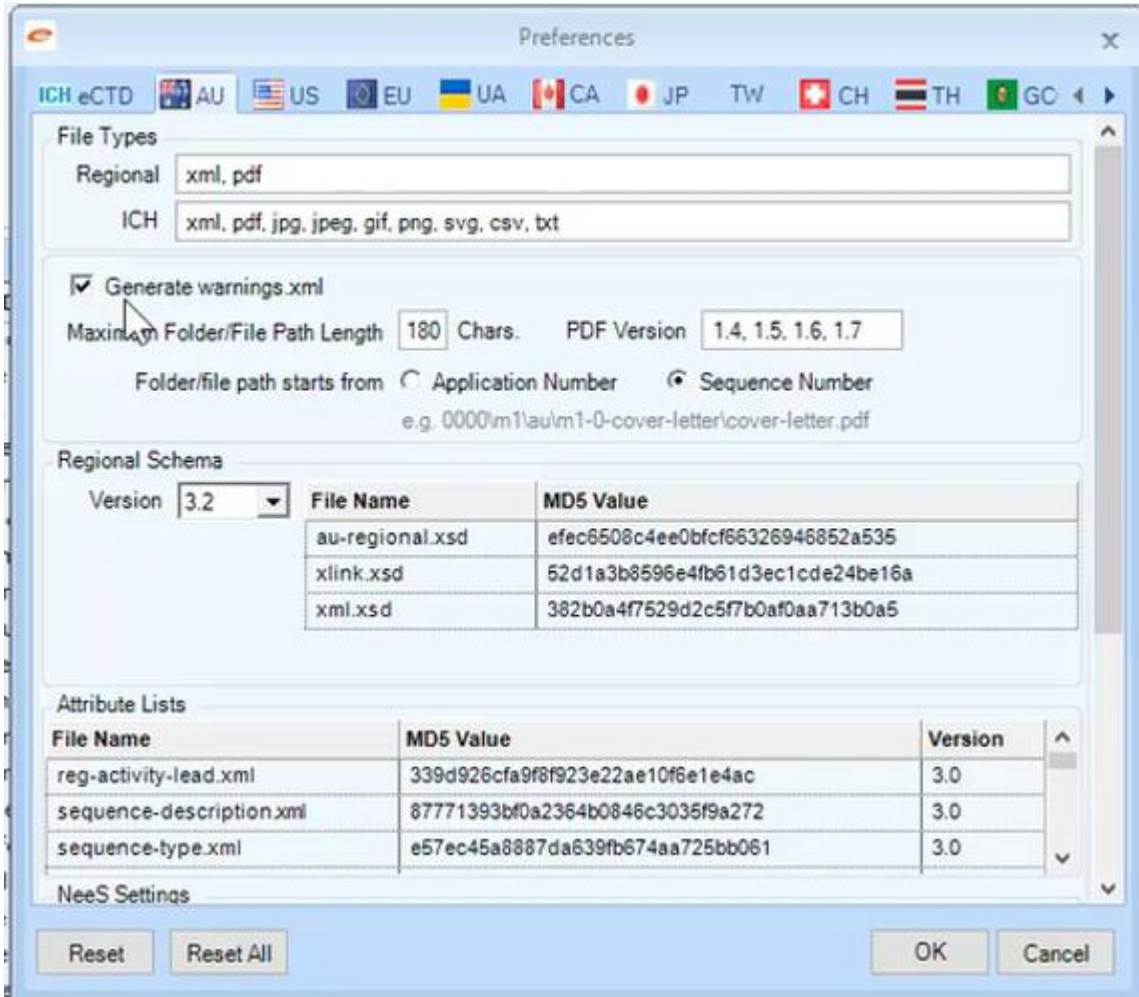
1. Open Ennov InSight Validator and select the Australia profile.



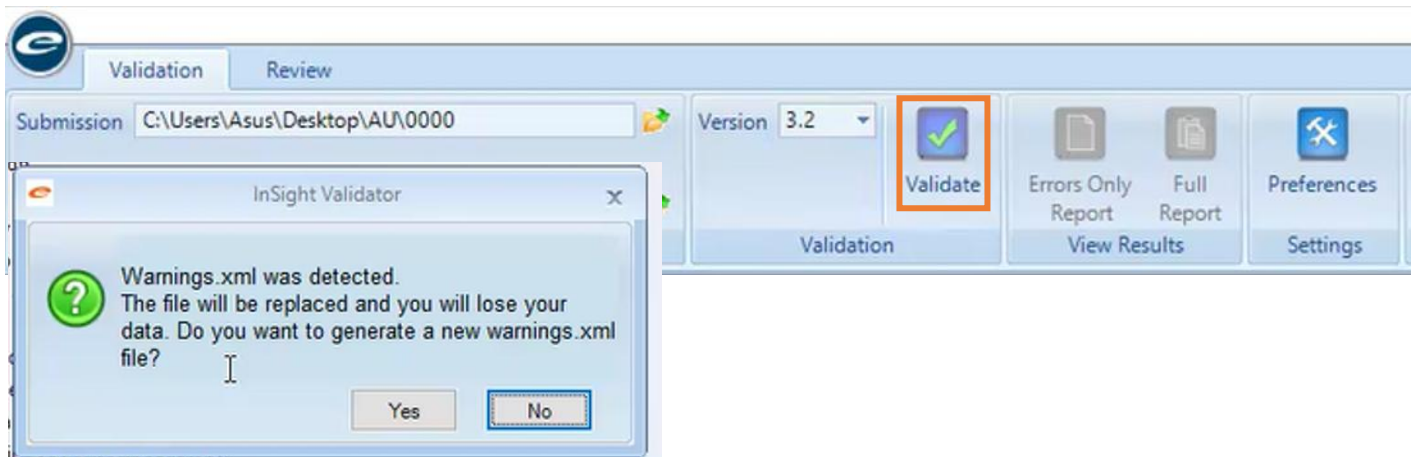
2. Select the relevant sequence folder that the version number is set to 3.2



3. Navigate to Preferences and click on it to open.
4. Tick the Generate warnings.xml checkbox. Then click OK.



5. Click on the Validate button. If a warnings.xml has been generated before you will receive a pop-up message confirming if you wish to overwrite the existing warnings.xml. If not, then the system will proceed to validation. **If you have made comments to an existing warnings.xml it will be lost if you choose to overwrite it.**



- The user should now see a warnings.xml file in the output. If there are no validation criteria warnings which are applicable, then the warnings.xml will not be generated.

Name	Status	Date modified	Type	Size
m1	↻	07/07/2025 18:45	File folder	
m2	↻	07/07/2025 18:45	File folder	
m3	↻	07/07/2025 18:45	File folder	
m4	↻	07/07/2025 18:46	File folder	
m5	↻	07/07/2025 18:46	File folder	
util	↻	07/07/2025 18:46	File folder	
index.xml	↻	07/07/2025 18:45	XML File	63 KB
index-md5.txt	↻	07/07/2025 18:45	Text Document	1 KB
warnings.xml	↻	07/07/2025 18:45	XML File	63 KB

- The user can now open the warnings.xml in any text editing software and provide justification for the validation criteria warnings then save. (For illustration purposes they are highlighted in orange).

```
warnings.xml
1 <?xml version="1.0" encoding="utf-8"?>
2 <warnings-explained xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema">
3   <rule number="6.17">
4     <rule-description>Hyperlinks must 'Inherit Zoom'</rule-description>
5     <comment>Justification of warning text.</comment>
6   </rule>
7   <rule number="6.22">
8     <rule-description>PDF initial view must be correct</rule-description>
9     <comment>Justification of warning text.</comment>
10  </rule>
11 </warnings-explained>
```

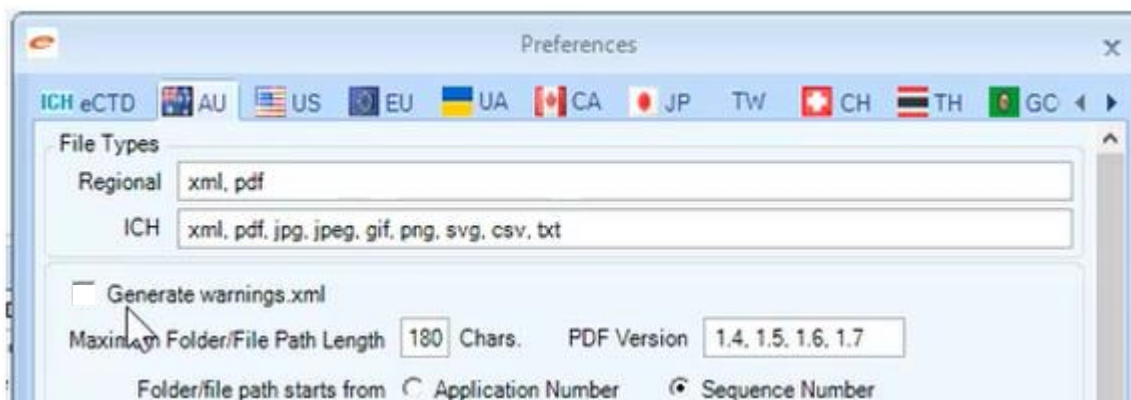
## 4.2 Considerations when working with warnings.xml

### 4.2.1 User has a pre-existing warnings.xml which they want to keep.

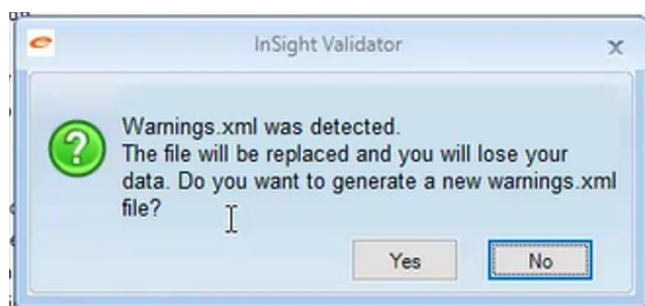
If the user has a pre-existing warnings.xml and does not wish for it to be overwritten, they will need to follow the steps below. This might be the case if the user is validating through InSight Validator as a back up for their primary validator or vice-versa.

There are two options:

1. The user can uncheck the 'Generate warnings.xml' option in preferences



2. Click the 'no' option in the pop-up which displays after clicking validate.



### 4.2.2 User has a validation 2.10 error.

In InSight Validator you may get an error for validation criteria 2.10 in the following cases.

1. Scenario: There are priority warnings but no warnings.xml file.  
Solution: Complete steps in section above to generate warnings.xml
2. Scenario: There are no priority warnings but a warnings.xml files exist.  
Solution: Delete the warnings.xml file from the sequence folder.

### 4.2.3 Validation Criteria Groups and Warning.xml

If the user validates the submission with 1 or more validation criteria groups disabled, it is important to note that the warnings.xml file will not be generated. To ensure generation user must have selected all validation criteria.

