

Progress Report on SMS and Audit Section

OPI for SMS and Audit Section

Current Status on SMS and Audit Section

- In the SMS and Audit Section, all texts related to Phase 1 and Phase 2 (provisions based on the FRAV/VMAD integrated document) were approved at the Seoul meeting.
- Currently, Phase 3 has begun, which is new proposals that are not in the FRAV/VMAD integrated document. Open items are being collected and discussed.
- After the Seoul meeting, it was agreed that the following provisions would be included in the regulation under the Audit section.

The reporting of the audit of the safety management system of the manufacturer shall be performed in such a manner that allows traceability, e.g. versions of documents inspected are coded and listed in the records of the assessor.

- We would like to incorporate the above text into the appropriate place of the Audit section in the ADS-IWG Base document.

Open Item List

➤ SMS Section

1	<p>Providing safety-relevant information to relevant parties</p> <p>The manufacturer shall have processes for providing safety-relevant information to relevant parties as needed, enabling them to meet their legal obligations.</p>
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➤ Audit Section

2	<p>Certificate of Compliance for the SMS</p> <p>Contracting Parties shall appoint an Approval Authority to carry out the assessment of the manufacturer and to issue a Certificate of Compliance for the SMS.</p>
3	<p>Certificate of Compliance extension period for 3 years</p> <p>The Initial assessment has a validity of one year. After a positive assessment at the end of this first year the Approval Authority may extend the compliance statement for the period of max 3 years. from the date of deliverance of the certificate unless it is withdrawn.</p>
4	<p>6.1.2 Audit of the SMS</p> <p>6.1.2.1 Review of the Safety Policy</p> <p>6.1.2.2 Review of the Risk Management</p> <p>6.1.2.3 Review of Design and Development, Production, and post deployment processes</p> <p>6.1.2.4 Review of the Safety Assurance</p> <p>6.1.2.5 Review of the Safety Promotion</p>
5	<p>6.1.3 Audit process</p> <p>6.1.3.1 Initial SMS implementation/Certification audit:</p> <p>6.1.3.2 Surveillance</p> <p>6.1.3.3 Observations and Findings</p>