SAMNET Synthesis Report

Safety Management and Interoperability

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Document abstract: This document is the SAMNET synthesis report. This deliverable describes the main final results of SAMNET activities from January 2003 to December 2005 and related to Safety management and certification issues: CSMs, CSIs, CSTs, occupational safety, safety management system, harmonisation of operational rules and cross acceptance.

This synthesis report groups together the final reports of the activity areas and takes into account the results of various workshops and user group meetings.

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1 Overview

1.1 Context

The progressive establishment of a liberated European railway network requires efficient Community action in respect to the technical regulations applicable to railways while taking into account the technical and safety aspects. In order to facilitate this common railway market, Council Directive 91/440/EEC [Ref 4] advocates a progressive “opening up of rights of access to the infrastructure to any licensed Community railway undertaking”.

The technical and operational fragmentation as well as the geographical differences between the railway systems of the Member States is a major hurdle for the development of a single European railway. Consequently, Council Interoperability Directives (96/48/EC [Ref 2] and 2001/16/EC [Ref 3] as amended by 2004/50/EC) have defined essential requirements and established a mechanism for explaining mandatory technical specifications for interoperability. Furthermore, the European Railway Safety Directive (2004/49/EC) [Ref 1] emphasises the development of a Safety Management System, Common Safety Indicators, Common Safety Targets and Common Safety Methods through independent technical expertise and requires the development of a harmonised format for safety certificates/authorisations and their application.

1.2 SAMNET objectives

SAMNET “Safety Management and interoperability thematic NETwork for railway systems” is a thematic network launched by the European Commission in January 2003. It formed part of the thematic network objectives defined in the “Competitive and Sustainable Growth” programme as part of the Fifth Framework Programme of the European Commission.

The SAMNET project addresses “Key action 2: Sustainable mobility and intermodality”. It focuses on the SMART rail Single MArket for Rail Transport services and deals with the approach to railway safety management. The primary objectives of the SAMNET thematic network are to accompany EU-harmonisation activity in the railway transport field and to share the usability of Trans–European safety requirements. SAMNET addresses the Safety Directives issues and should help in their development. The activities within the SAMNET thematic network are based on the EU Directives for Interoperability (High Speed and Conventional Rail), Safety Directive and TSIs. It addressed the following five main objectives:

- To facilitate the dialogue between various parties in relation to operational safety and interoperability and regulation aspects.
- To co-ordinate the approaches to safety and certification activities including a link with the SAMRAIL project and a link to other relevant thematic networks relating to the safety.
- To support all strategic research and development related to safety management in the context of the ERRAC “Joint Strategy for European Rail Research –2020: Towards a Single European Railway System”.
- To identify the most promising results of safety related research activities and recommend which steps should be taken in order to establish a new optimised safety approach.
• To promote knowledge, experiences and good practice collected during the project to a wide variety of audience including Regulatory Authorities, Transport Authorities, Transport Operators, Managers of Infrastructure, Standardisation Bodies, Notified Bodies, Universities and Research Centres, Passenger Organisations, Manufacturers and Engineering Companies.

1.3 Relationship between SAMNET and SAMRAIL projects

SAMNET and SAMRAIL were European projects launched by the Commission in 2003 to investigate and propose approaches to specify and implement the requirements identified in the Safety Directive. In particular, issues concerning policies on Safety Management System, Common Safety Indicators, Common Safety Targets and Common Safety Methods were addressed by these projects.

SAMRAIL stands for Safety Management in Railways and ended its activities in July 2004.

SAMNET stands for Safety Management and interoperability thematic Network for railways system. The project ended its activities in December 2005.

The main task of the SAMNET project was to improve the output from SAMRAIL and by means of large-scale involvement of European players in the work and by coordinating harmonised concepts and practices, to obtain agreement on given topics, such as safety targets, safety methods and safety indicators. The relationship between the two can be summarised as:

- Dissemination of SAMNET and SAMRAIL findings and seek opinions of other stakeholders, through:
  - easy-to-understand guidance notes on Safety Directive issues and SAMNET/SAMRAIL findings so as to create awareness among the policy makers, management and staff
  - workshops on individual topics, seeking opinions from the experts and raising awareness
  - case studies to check if the suggested approaches (SMS, CSM, CST, CSI and certification processes) are workable

- Plan and suggest position papers on the technical issues identified in SAMRAIL.

- Liaise with different trade and technical associations and organisations, such as AEIF, EIM, CER, ERRAC, ILGGRI and identify their stances on the issues raised by SAMNET and SAMRAIL.

1.4 Document summary

This synthesis report summarises the results of SAMNET achieved during the three years of the project (January 2003 to December 2005). It takes into account the main outputs from the SAMRAIL project that completed its work in July 2004. This report contains the overview of the results of activities carried out by SAMNET working groups.

There were four working groups covering the four items that were the central point of SAMNET’s activities. These were:

1. Research strategy plan related to safety management
2. Operational safety and regulations covering safety management and economic aspects, operational rules, accident/incident and Common Safety Indicators (CSIs) and Common Safety Targets (CST).
3. Safety management – development of Common Safety Methods (CSM), applicability of guidelines for Safety Management System (SMS) and occupational safety policies

4. Certification and cross acceptance related to certification and cross acceptance of Rolling Stock, applicability of standards and best practices.

This report is divided into ten sections. Each section is based on the results achieved by the SAMNET work and contains a summary of results. It gives some positions of SAMNET members based on discussions with project partners, other groups and on a large number of consultations through workshops and user group meetings. The general conclusion is presented in section eight.

The 10 sections are:

- An executive summary.
- SAMNET technical structure section presenting the SAMNET project organisation and structure.
- “Consultation and dissemination” section presenting the dissemination and consultation activities needed to develop a consensus on main findings. It describes the meetings, workshops and user group activities organised to discuss safety directives issues.
- The “Operational and safety regulations issues” section covering the safety policies related to safety management development, occupational safety aspects and the impact of publication of the operations TSI on safety management.
- “Common Safety Targets; Indicators and Methods”. This section deals with the main results of the SAMNET project in respect to CST, CSI and CSM issues. The results of dedicated workshops in these issues are also presented.
- The “Cross - Acceptance” section provides a number of key elements for the certification and authorisation process and requirements and suggests the development of common references for rolling stock cross acceptance. The results of dedicated workshops in these issues are also presented.
- “Research strategy”. This section highlights the next step research items which the project suggests are needed for improving the management of railway safety taking account of interoperability requirements and implementation.
- The “Conclusion” gives the main findings of the SAMNET project on safety management.
- “Definitions and acronyms”. This section defines the terms used in this report.
- The “References” section lists the reports produced by the SAMNET and SAMRAIL projects and the main documents used to develop the main findings of SAMNET.

In connection with many of the sections of this report, a number of positions have been developed by the project. These are published at the end of each relevant subsection. They take the form of a number of comments and positions taking into account not only safety directive requirements but also the opinions expressed during consultation with various external groups such as the UIC Safety Platform, ILGRI and other rail sector organisations. These are in some cases supported by further comments to aid understanding and future development.
2 SAMNET technical structure

2.1 Summary of SAMNET work packages

SAMNET activity was supported by SAMNET Work Packages dealing with the key items of Railway Safety Management. For each work package, an organisation was assigned the responsibility for leading the work in collaboration with SAMNET members.

<table>
<thead>
<tr>
<th>Work package</th>
<th>Work package title</th>
<th>Lead contractor</th>
<th>Persons month</th>
<th>Start month</th>
<th>End month</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP0</td>
<td>Project Management</td>
<td>INRETS</td>
<td>12</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>WP1.1</td>
<td>Research strategy plan</td>
<td>INRETS</td>
<td>8</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>WP1.2</td>
<td>Operational and safety regulations and interoperability issues</td>
<td>UIC</td>
<td>23</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>WP1.3</td>
<td>Safety management and certification issues</td>
<td>INRETS</td>
<td>29</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>WP1.4</td>
<td>Dissemination and Exploitation</td>
<td>UIC</td>
<td>22</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>94</td>
</tr>
</tbody>
</table>

Table 1: Work packages and responsibilities

2.1.1 WP0: Project Management

This is related to the overall project activities for the quality, cost and delivery schedules for completion of the overall technical activities in accordance with the contract.

2.1.2 WP1.1: Research strategy plan

The "strategy plan" work package is related to the railway safety and interoperability directives and the research and development strategy of safety management in the railway sector. The main focus is on identifying any necessary future research activities and supporting the decisions taken by giving recommendations in this domain. The “Strategy Research” working group (WG.1) was in charge of developing and consolidating the results.

The results summary of this WP are presented in section 7 of this report.

<table>
<thead>
<tr>
<th>WG1: Strategy Research</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman: A.Hale (TU-Delft)</td>
<td>Develop a research strategy document related to safety management using all the deliverables of SAMNET and SAMRAIL and other relevant documents.</td>
</tr>
<tr>
<td>Secretariat: J.Rodriguez (INRETS)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Research strategy group.
2.1.3 WP1.2: Operational and safety regulations and interoperability issues

The main goal was to facilitate dialogue between various parties in relation to operational safety, interoperability and regulations aspects. This WP worked in close contact with SAMRAIL, improving the outputs and harmonising the viewpoints on the respective topics. This WP focused on the operational, organisational and economic sides of safety management.

The working group “Operational safety and regulation (WG.2)” was responsible for developing and consolidating the results.

The results of this WP are presented in section 4 of this report.

<table>
<thead>
<tr>
<th>WG2: Operational safety and regulation</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman: P.J. Dupont (SNCF)</td>
<td>Develop operational safety position papers related to economic aspects, accident/incident data (CSI) and Common Safety Targets (CST) using the deliverables of SAMNET and SAMRAIL and other relevant documents.</td>
</tr>
<tr>
<td>Secretariat: L. Tordai (UIC)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Operational safety and regulation group

2.1.4 WP1.3: safety management and certification issues

The objectives of this work package were to co-ordinate R&D activities and to facilitate dialogue between various parties in relation to technical aspects of safety management. The activities were based on the EU Safety Directive and TSI requirements and included a link with the SAMRAIL project.

The examination of assessment and certification practices using CENELEC standards and the issues of cross acceptance procedures were also addressed. The working groups “Safety management (WG.3)” and “Certification and cross acceptance (WG.4)” were in charge of developing and consolidating the results.

The results of this WP are presented in section 5 of this report.

<table>
<thead>
<tr>
<th>WG3: Safety management</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman: S. Mitra (Atkins)</td>
<td>Develop Common Safety Methods (CSM) and applicability of guidelines for Safety Management System (SMS) using the deliverables of SAMNET and SAMRAIL and other relevant documents.</td>
</tr>
<tr>
<td>Secretariat: E. M. El Koursi (INRETS)</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Safety Management group

The results of this WP are presented in section 6 of this report.

<table>
<thead>
<tr>
<th>WG4: Certification and cross acceptance</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman: R. Vom Hövel (TUV-TAT)</td>
<td>Develop a position paper related to certification and cross acceptance of Rolling Stock using the deliverables of SAMNET and SAMRAIL and other relevant documents.</td>
</tr>
<tr>
<td>Secretariat: A. Stuparu (Mrs) (INRETS)</td>
<td></td>
</tr>
</tbody>
</table>

Table 5: Certification and cross acceptance group.
2.1.5 WP1.4: Dissemination and exploitation

The dissemination objective was to promote knowledge, experience and best practices collected during the project. It aimed to co-ordinate the dissemination and exploitation of the results related to the SAMNET and SAMRAIL projects.

User Group workshops were organised every 6 months and a Web-Site was created in co-ordination with project partners/members.

Publications, Conferences, Lectures on safety management and the project were undertaken during the project. The exploitation policy is addressed.

The results of this WP are presented in section 3.

2.2 SAMNET membership

The SAMNET project involved two principle contractors INRETS and UIC (ERRI) with a total of 32 member organisations. There were two types of members:

- Initial members involved from the beginning of the project
- Members who joined SAMNET consortium during its lifetime.

<table>
<thead>
<tr>
<th>Contractors</th>
<th>Members (MB)</th>
<th>Mission</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) INRETS</td>
<td>MB1:DTF (DK)</td>
<td>Danish Transport research institute</td>
<td>Research institutes and Universities</td>
</tr>
<tr>
<td></td>
<td>MB2:TUBSIFRA/IFEV(D)</td>
<td>TU of Braunschweig</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB3:TU Dresden (D)</td>
<td>TU of Dresden</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB4:TU Delft (NL)</td>
<td>TU of DELFT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB5:ALSTOM (F)</td>
<td>ALSTOM</td>
<td>Manufacturers</td>
</tr>
<tr>
<td></td>
<td>MB7:SECTOR (F)</td>
<td>Sector</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB8:SIEMENS (D)</td>
<td>Siemens Transportation Systems</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB9:ANSALDO (I)</td>
<td>ANSALDO BREDA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB24: BOMBARDIER(B)</td>
<td>Bombardier transportation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB10: ATKINS (UK)</td>
<td>WS Atkins Rail limited.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB11:TÜV-TIT (D)</td>
<td>TÜV Intertraffic GmbH,</td>
<td>Assessors and Notified bodies</td>
</tr>
<tr>
<td></td>
<td>MB12:TÜV-TIS (D)</td>
<td>TÜV Industrie-Service GmbH,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB13:CERTIFER (F)</td>
<td>Agence de certification Ferroviaire</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB14: EBC (D)</td>
<td>Notified Body Interoperability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MB15: IVW (NL)</td>
<td>Railway Safety Authority</td>
<td></td>
</tr>
</tbody>
</table>
Table 6: Initial SAMNET members.

The following stakeholders joined the SAMNET consortium in 2004 and 2005.

Table 7: New members joined SAMNET project
3 Consultation and dissemination

3.1 Project meetings

During the SAMNET project a number of working group meetings (WG1, WG2, WG3 and WG4), coordination meetings with ERRI, ATKINS, UIC and EC were organised to develop, review and approve the deliverables and the position papers. [Ref 27]; [Ref 28]; [Ref 30]; [Ref 31] and [Ref 32].

According to the SAMNET technical annex and the SAMNET work plan (2005) the technical and steering committees have held various meetings to discuss and to review the draft deliverables and SAMNET strategy and work plan.

Also the SAMNET coordination team has held various meetings with officers of DG-TREN to examine work progress. Furthermore, SAMNET members organised a number of internal meetings to disseminate and analyse the SAMNET deliverables.

3.2 SAMNET User Group workshops

Six SAMNET User Group workshops [Table 8] were organised to present, disseminate and get feedback about the intermediate results related to SMS, CSMs, CSTs, CSIs, cross acceptance and research strategy on safety management.

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Date and location</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st User Group</td>
<td>1st July, 2003</td>
<td>This first workshop aimed to provide general information on the SAMNET and SAMRAIL projects, main results of the projects obtained during the first period of the project and an overview of interfaces of general processes on railway field like Interoperability and Technical Specification of railway system versus Safety Management System and the European Safety Directive. 103 attendees from 19 countries (18 European countries plus Japan) [Figure 1]. The conclusions of this workshop are given in document [Ref 45] D1.4.1 (1): L.Tordai “SAMNET, 1st User group workshop, Report and Conclusions” SAMNET/ERRI/LT/WP1.4/D1.4.1(1)/V1, 8/07/2005.</td>
</tr>
<tr>
<td>2nd User Group</td>
<td>15th January, 2004</td>
<td>The main objective of the 2nd user group workshop was to present the results obtained from the SAMNET and SAMRAIL projects in the 6 months between July 2003 and December 2003. The workshop was dedicated to the safety management system. 95 attendees from 19 countries (18 European countries plus Japan) [Figure 1]. The conclusions of this workshop are given in the document [Ref 46] D1.4.1 (2): L.Tordai and E.M.El Koursi “SAMNET, 2nd User group workshop”</td>
</tr>
</tbody>
</table>

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### Table 8: User group workshops

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Date and location</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rd User Group</td>
<td>3rd June, 2004 Budapest, Hungary</td>
<td>Despite providing an overview of project activity in the first half of 2004, the workshop had a special importance because the activity of SAMRAIL project was due to end by the end of July 2004. The user group was dedicated to SMS, TSI development and cross acceptance. The third user group meeting was well attended: 95 attendees from 19 countries (18 European countries plus Japan) [Figure 1]. The conclusions of this workshop are given in the document [Ref 47] D1.4.1 (3): L.Tordai and E.M.El Koursi, “SAMNET/SAMRAIL 3rd Workshop Budapest 03.06.2004 Report and conclusions”, SAMNET/ERRI/LTR/WP1.4/D1.4.1(3)/V1, 26/07/2004.</td>
</tr>
<tr>
<td>4th User Group</td>
<td>18th January, 2005 London, UK</td>
<td>This user group was dedicated to SMS, CST, CSI, CSM, TSI and cross acceptance development as well as providing an overview of the SAMRAIL conclusions. This user group meeting was very well attended: 105 attendees from 17 countries (+ Japan) [Figure 1]. The conclusions of this workshop are given in the document “SAMNET, 4th User group workshop: report and conclusion [Ref 48] D1.4.1 (4) : L.Tordai and E.M.El Koursi “SAMNET 4th Workshop London, 18.01.2005 Report and conclusions”, SAMNET/UIC/LT/WP1.4/D1.4.1(4)/V1, 16/02/2005.</td>
</tr>
<tr>
<td>5th User Group</td>
<td>9th June, 2005 Copenhagen, Denmark</td>
<td>This user group meeting focused on rolling stock acceptance, CSM, CST, CSI and research strategy aspects as well as providing an overview of SAMNET project progress in the first half of 2005. 81 attendees from 54 companies participated in this meeting [Figure 1]. The conclusions of this workshop are given in the document [Ref 49] D1.4.1 (5): L.Tordai and E.M.El Koursi “SAMNET/SAMRAIL 5th Workshop Copenhagen, 09.06.2005 Report and conclusions” SAMNET/UIC/LT/WP1.4/D1.4.1(5)/V1</td>
</tr>
<tr>
<td>6th User Group</td>
<td>6th December, 2005 Lille, France</td>
<td>The main objective of the sixth and final User Group workshop was to present the final results of SAMNET project. The number of participants was 105 representing 21 countries [Figure 1]. The conclusions of this workshop are given in the document [Ref 49] D1.4.1 (6): L.Tordai and E.M.El Koursi “SAMNET/SAMRAIL 6th Workshop in Lille. Report and conclusions are presented in the document referenced ”SAMNET/UIC/LT/WP1.4/D1.4.1(6)/V1.</td>
</tr>
</tbody>
</table>

The figure below gives the repartition by type of organisation (RUs, IMs, NoBo, etc.) attending each SAMNET user group. Each user group involved at least 50 companies from at least 17 and up to 19 member states.
<table>
<thead>
<tr>
<th>Type of company participation (rates)</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>5th</th>
<th>6th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associations</td>
<td>12%</td>
<td>10%</td>
<td>4%</td>
<td>7%</td>
<td>6%</td>
<td>7%</td>
</tr>
<tr>
<td>EC</td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Manufacturers</td>
<td>14%</td>
<td>13%</td>
<td>19%</td>
<td>5%</td>
<td>13%</td>
<td>11%</td>
</tr>
<tr>
<td>Infrastructure Managers</td>
<td>13%</td>
<td>10%</td>
<td>8%</td>
<td>9%</td>
<td>6%</td>
<td>13%</td>
</tr>
<tr>
<td>Notified bodies and Assessors</td>
<td>15%</td>
<td>13%</td>
<td>23%</td>
<td>31%</td>
<td>30%</td>
<td>31%</td>
</tr>
<tr>
<td>Railway Undertakings</td>
<td>25%</td>
<td>31%</td>
<td>21%</td>
<td>24%</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td>Universities &amp; Research Centres</td>
<td>19%</td>
<td>19%</td>
<td>23%</td>
<td>20%</td>
<td>32%</td>
<td>23%</td>
</tr>
</tbody>
</table>

| Participation rate at SAMNET user groups by organisation type |

Participation rate by entity

**Figure 1:** Participation rate by entity
### 3.3 Dedicated SAMNET workshops

Eight dedicated workshops were organised to deal with specific items such as Rolling Stock cross acceptance and SMS.

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Date and location</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st specific workshop</td>
<td>14th November 2003</td>
<td>Presentation of SAMNET and SAMRAIL results and discussion and debate on the draft SMS Guidelines. 52 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>Utrecht, Netherlands</td>
<td></td>
</tr>
<tr>
<td>2nd specific workshop</td>
<td>27th November 2004</td>
<td>Workshop on rolling stock cross acceptance. This workshop was dedicated to the presentation of various examples (French, British, German and Dutch) 24 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>UNIFE, Brussels</td>
<td></td>
</tr>
<tr>
<td>3rd specific workshop</td>
<td>1st December, 2004</td>
<td>Presentation of SAMNET and SAMRAIL results and discussion and debate on SMS Guidelines document and CST, CSM, CSI and cross acceptance development. 47 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>Braunschweig, Germany</td>
<td></td>
</tr>
<tr>
<td>4th specific workshop</td>
<td>8th April, 2005</td>
<td>This workshop was dedicated to the Rolling stock acceptance procedure. Various examples of bilateral acceptance were presented. 58 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>Paris-UIC, France</td>
<td></td>
</tr>
<tr>
<td>5th specific workshop</td>
<td>18th May, 2005</td>
<td>This specific workshop was organised to discuss and develop the Common Safety Methods (CSM). 38 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>London, UK</td>
<td></td>
</tr>
<tr>
<td>6th specific workshop</td>
<td>30th June, 2005</td>
<td>Presentation of SAMNET and SAMRAIL results and discussion and debate on SMS Guidelines document and CST, CSM, CSI and cross acceptance development. 43 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>Warsaw, Poland</td>
<td></td>
</tr>
<tr>
<td>7th specific workshop</td>
<td>20th September, 2005</td>
<td>This specific workshop was organised to present the SAMNET results on CSM, CST and CSM. Three parallel working sessions were established to consider Common Safety Methods (CSM), Common Safety Methods (CSM) and Common Safety Methods (CSM) and then to consider in plenary session the interfaces. 80 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>Lisbon, Portugal</td>
<td></td>
</tr>
<tr>
<td>8th specific workshop</td>
<td>13th October, 2005</td>
<td>This workshop was dedicated to the Rolling stock acceptance procedure. Various examples of bilateral acceptance were presented and the first result of task force was also discussed. 55 participants attended this workshop.</td>
</tr>
<tr>
<td></td>
<td>Florence, Italy</td>
<td></td>
</tr>
</tbody>
</table>

*Table 9: Dedicated workshops*
3.4 Case studies

Three case studies were used to develop and to refine the proposed approaches (e.g. SMS, CST and cross acceptance). Various meetings were organised to discuss the approaches proposed by SAMNET/SAMRAIL partners:


- The Woippy-Manneheim freight traffic flow was used to develop the applicability of CSTs [Ref 42] D1.3.3: C.Cassir, P-J.Dupont, P.Galley, H.Kuijlen, E.Lemaire, L.Lopez, A.Patacchini, G.Vanstaen, S.Reinartz, C.Salander “Specific CSTs report Case study”, SAMNET/RFF/PGL/WP1.3/D1.3.3/V0.12, 10/06/2005

- ICE3/TGV POS – the rolling stock being proposed for the Paris – Frankfurt high speed service was studied as part of the development the rolling stock cross acceptance approach [Ref 44] D1.3.5: A.Stuparu and N.Duquenne “Cross Acceptance of Vehicles under the Interoperability & Safety Directives”, SAMNET/INRETS/AS/WP1.3/D1.3.5/V1.2, 24/06/2005.

3.5 Presentations to and consultation with other groups

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Date and place</th>
<th>Main activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERRAC</td>
<td>24th April 2003, Brussels</td>
<td>• SAMNET/SAMRAIL presentations</td>
</tr>
<tr>
<td></td>
<td>23rd June, 2003, Brussels</td>
<td>• Coordination of safety activities conducted by ERRAC (WT3), Safety Platform and</td>
</tr>
<tr>
<td></td>
<td>1st December, AEIF, Brussels</td>
<td>SAMNET groups</td>
</tr>
<tr>
<td></td>
<td>28th September 2004, Bonn</td>
<td>• Discussion about the assessment of an SMS with the representatives from ILGGRI,</td>
</tr>
<tr>
<td></td>
<td>17th May 2005, London</td>
<td>Eurotunnel and safety platform groups</td>
</tr>
<tr>
<td>Safety Platform</td>
<td>29th January 2003, Berlin</td>
<td>• SMS presentation and discussion</td>
</tr>
<tr>
<td></td>
<td>11th February 2003, London</td>
<td>• CST, CSM and CSI discussion</td>
</tr>
<tr>
<td></td>
<td>8th April 2003, Florence</td>
<td>• Occupational safety aspects</td>
</tr>
<tr>
<td></td>
<td>21st May 2003, Brussels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4th February 2004, Paris</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17th June, 2005, Paris</td>
<td></td>
</tr>
<tr>
<td>UIC Safety Directors</td>
<td>4th May 2004, Paris</td>
<td>• SMS presentation and discussion</td>
</tr>
<tr>
<td>Article 21 Committee</td>
<td>2nd July 2004, Brussels</td>
<td>• SAMNET/SMS presentation</td>
</tr>
<tr>
<td>CER, EIM, AEIF, UITP and UNIFE</td>
<td>Consultations were made throughout the project with either representatives or member companies from each of these organisations present at workshops and user group meetings.</td>
<td></td>
</tr>
</tbody>
</table>
Various initiatives have been made by SAMNET members to disseminate and to support the SAMNET and SAMRAIL results. DB AG, for example, set up a national support group in 2003 which aimed to disseminate the results of SAMNET and SAMRAIL as well as getting feedback from different areas of railway entities such as the Ministry of transport, national safety authority, railway associations and railway industry. For the information of this support group - built up from representatives of the above mentioned railway entities - two meetings were organised in 2004.

Also information exchanges between SAMNET/SAMRAIL and CENELEC working group WG 8 were established to develop a safety guideline for railway applications according to EN 50126. (e.g. information to members contributing to chapter 5 and 6 which deals with setting up of safety targets and risk analysis).

### 3.6 Conferences and congress

<table>
<thead>
<tr>
<th>Conferences/congress</th>
<th>Date and subject</th>
<th>Venue</th>
</tr>
</thead>
<tbody>
<tr>
<td>WCRR Congress</td>
<td>28th September to 1st October 2003</td>
<td>Edinburgh, Scotland</td>
</tr>
<tr>
<td></td>
<td>o SMS presentation</td>
<td></td>
</tr>
<tr>
<td>TILT Congress</td>
<td>5th to 4th December 2003</td>
<td>Lille, France</td>
</tr>
<tr>
<td></td>
<td>o SAMNET presentation</td>
<td></td>
</tr>
<tr>
<td>Conference on Interoperability</td>
<td>25th January 2004</td>
<td>Warsaw, Poland</td>
</tr>
<tr>
<td></td>
<td>o Liaison between safety and interoperability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o SAMNET impact on safety and interoperability</td>
<td></td>
</tr>
<tr>
<td>Railway conference</td>
<td>May 2004.</td>
<td>Zelina, Slovakia</td>
</tr>
<tr>
<td></td>
<td>o SAMNET results on cross acceptance</td>
<td></td>
</tr>
<tr>
<td>Rail safety Operation conferences</td>
<td>24th to 25th June 2004.</td>
<td>Brussels, Belgium</td>
</tr>
<tr>
<td></td>
<td>o SMS presentation</td>
<td></td>
</tr>
<tr>
<td>Risk Management Forum</td>
<td>30th June 2004.</td>
<td>Nottingham, UK</td>
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<tr>
<td></td>
<td>o CST for the Railways</td>
<td></td>
</tr>
<tr>
<td>UIC-Safety seminar</td>
<td>14th September 2004.</td>
<td>Paris, France</td>
</tr>
<tr>
<td></td>
<td>o SAMNET presentation</td>
<td></td>
</tr>
<tr>
<td>SIFER</td>
<td>15th March 2005.</td>
<td>Lille, France</td>
</tr>
<tr>
<td></td>
<td>o SAMNET presentation</td>
<td></td>
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<tr>
<td>UIC- SIAFI seminar</td>
<td>20th to 24th September 2005.</td>
<td>Paris, France</td>
</tr>
<tr>
<td></td>
<td>o SAMNET presentation</td>
<td></td>
</tr>
<tr>
<td>Railway conference</td>
<td>23rd to 25th May 2005.</td>
<td>Zelina, Slovakia</td>
</tr>
<tr>
<td></td>
<td>o SAMNET results and CSTs approach presentations</td>
<td></td>
</tr>
<tr>
<td>Safety Seminar</td>
<td>10th to 12th October 2005.</td>
<td>Cape Town, South Africa</td>
</tr>
<tr>
<td></td>
<td>o SAMNET presentation</td>
<td></td>
</tr>
<tr>
<td>Q&amp;Test conference</td>
<td>24th to 26th October 2005.</td>
<td>Bilbo, Spain</td>
</tr>
<tr>
<td></td>
<td>o SMS presentation</td>
<td></td>
</tr>
</tbody>
</table>

Table 11: conferences and congress
3.7 SAMNET / SAMRAIL Web-Site

The Web-sites SAMNET and SAMRAIL are accessible with the following addresses:

http://www.samnet.info
http://www.samrail.org

3.7.1 Access data to SAMNET website from January to December 2005

Here above some figures from SAMNET website consultation statistics. The figure below represents the evolution of the number of pages consulted per month. The period covers from January 2003 to November 2005.

![SAMNET website access data from January 2003 to February 2006](image)

Figure 2: SAMNET web site visits
### 3.8 SAMNET deliverables

<table>
<thead>
<tr>
<th>WPs</th>
<th>Deliverables</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP0.1 Project Management</td>
<td>SAMNET Glossary, April 2003, SAMNET/INRETS/ELK/WP0/SAMNET.</td>
<td>9th April 2003</td>
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<td>SAMNET work plan, Period January 2005 to December 2005”</td>
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<td>4th March 2005</td>
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<td>SAMNET/INRETS/ELK/WP0/D1.0.4/V0</td>
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<td>D1.0.1</td>
<td>Project Brochure</td>
<td>30th June 2003</td>
<td>4th March 2005</td>
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<td>D1.0.2</td>
<td>SAMNET quality plan</td>
<td>15th April 2003</td>
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<td>D1.0.3</td>
<td>SAMNET project plan</td>
<td>19th June 2003</td>
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<td>E.M.El Koursi “Six monthly Progress Report Period n°1: From 01.01.2003 to 30.06.2003”</td>
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<td>30th June 2003</td>
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<td>D1.0.6 and D1.0.7</td>
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<td>D1.0.8</td>
<td>E.M.El Koursi “Six monthly Progress Report Periods n°5 From 01.01.2005 to 30-06-2005”</td>
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<tr>
<td>WP1.1 Research strategy plan</td>
<td>D1.1.1 Ph.Bon et Ch.Cassir, “Overview of National and European projects”, SAMNET/INRETS/PB/WP1.1/D1.1.1/V3,</td>
<td>12th February 2004</td>
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<td></td>
<td>D1.1.2 N.Duquenne “Mapping of competences for safety in railway Status on 2004”</td>
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<td>4th March 2005</td>
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<td>SAMNET/INRETS/ND/WP1.1/D1.1.2/V3</td>
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<td>D1.1.3 J.Rodriguez, A.hale and all, “Progress report on strategy plan for research”</td>
<td>20th March 2005</td>
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<td>7th November 2005</td>
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<td>E.Lemaire and L.Tordai “Report on comparison of safety policies” SAMNET/INRETS/ELM/WP1.2/D1.2.1/V4,</td>
<td>16th July 2003</td>
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<td>L.Tordai, G.Gavrila et E.M.El Koursi “Economic Aspects of Safety Management System and Interoperability”, SAMNET/ERRI/TOR/WP1.2/D1.2.2/V1,</td>
<td>March 2005</td>
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<td>D1.2.3</td>
<td>L.Tordai “Common Safety Targets and Common Safety Indicators” SAMNET/UIC/TOR/WP1.2/D1.2.3/V1</td>
<td>June 2005</td>
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<td>D1.2.4</td>
<td>L.Tordai and E.M.El Koursi “Report on harmonisation of operational rules and impact of TSI”, SAMNET/UIC/TOR/WP1.2/D1.2.4/V1,</td>
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<td>D1.2.5</td>
<td>E.M.El Koursi “SMS assessment criteria, Position paper”, SAMNET/INRETS/ELK/WP1.2/D1.2.5/V1</td>
<td>5th July 2005</td>
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<td>WPs</td>
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<td>L. Tordai “SAMNET, 1st User group workshop, Report and Conclusions”</td>
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<td>and</td>
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<td>L. Tordai and E.M. El Koursi, “SAMNET/SAMRAIL 3rd Workshop Budapest 03.06.2004 Report and conclusions”, SAMNET/ERRI/LT/WP1.4/D1.4.1(3)/V1</td>
<td>26(^{th}) July 2004</td>
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<td></td>
<td>D1.4.1 (5)</td>
<td>L. Tordai and E.M. El Koursi “SAMNET/SAMRAIL 5th Workshop Copenhagen, 09.06.2005 Report and conclusions”, SAMNET/UIC/LT/WP1.4/D1.4.1(5)/V1</td>
<td>15(^{th}) September 2005</td>
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<td>L. Tordai and E.M. El Koursi “Dissemination and Exploitation Plan”</td>
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4  Operational and safety regulations issues

4.1  Safety policies

4.1.1  Development of a liberated and safe European rail system

The 2001 White Paper [Ref 8] proposed to revitalise railways in the EU. The Trans-European Rail Network is made up of infrastructure in all the member states. It is interconnected within Europe and to neighbouring countries but this network exhibits a low interoperability level. Whilst there is through working of rolling stock, in most cases infrastructure, operating procedures and safety are not currently standardised. This situation is due to the fact that Europe comprises different member states whose railways have been developed in different historical, geographical, and cultural environments. The safety culture in different member countries is particularly variable. Whilst the majority of states operate under a standard track gauge, there is little or no standardisation of signalling or electrical supply systems.

The European Community regards its railways as an economic, efficient, environmentally friendly and very safe mode of transport. However, in the recent past, a substantial share of the railway market, especially freight, has been lost to other modes of transport. To compete on equal terms, the Community believes that its railways need a liberalised rail transport market similar to those in the civil aviation and maritime sectors. This approach requires some major changes in current practices, such as introduction of more self-regulation for companies operating in the rail sector, and increased openness and transparency in all member state railways. More integration of railway networks to facilitate cross-border operations is also needed. However, numerous and incompatible safety standards and practices present major obstacles to these aspirations.

The process of creating an internal European rail market has just started. The introduction of the first railway package of European Directives creates a common framework for access to railway infrastructure, for licensing and safety certification and for allocation of railway infrastructure capacity [Ref 5]. The European Directives on interoperability concern the global approach to all rail transport aspects, the second railway package, published in 2004, is designed to expand this approach by adding the safety aspects, extending the work on interoperability to new areas and putting it all into a comprehensive, clear and consistent context. The application of these new EU Directives on safety and interoperability [Ref 3] and [Ref 2] will nevertheless, have its financial dimension.

4.1.2  Safety directive

In recent years, the European Commission has begun to develop several railway initiatives, which are aimed at encouraging open market policy and harmonising the railways in Europe via technical and operational interoperability. This safety directive is designed to facilitate:
- Horizontal integration, i.e. interoperability of the networks facilitating smooth movement of passenger and freight trains,
- Vertical separation, e.g. between management of infrastructure and train operation and outsourcing of maintenance and support functions,
- A due and transparent certification process to improve safety approval and equipment acceptance.

The safety policy generally reflects the safety philosophy and safety culture of a country. The main influencing and powering factor is the transport market, which is part of the total market of a country, both national and international.

In this context, the European Commission began to develop several railway initiatives in order to harmonise the railways in Europe with interoperability and market opening as goals. These goals cannot be achieved without setting out high common safety standards. The European Safety Directive (SD) [Ref 1] aims at harmonising the regulatory structure that enforces railway operation and to ensure the development and improvement of safety on the Community’s railways by:

- Maintaining the global railway safety in each Member State,
- Harmonising the regulatory structure in the Member States,
- Defining responsibilities between the actors,
- Developing common safety methods, common safety indicators and common safety targets,
- Requiring the establishment, in every Member State, of national safety authorities and national bodies for accident investigation,
- Defining common principles for the management, regulation and supervision of railway safety.

The Directive describes the actors involved in the management of railway safety, a harmonised structure of the safety management and the responsibilities of each actor within it.

The roles of:

- European Infrastructure Managers
- European Railways Undertakings
- Railway Safety Authorities of European Member States
- Investigating Bodies of European Member States
- European Members States
- The European Railway Agency
- The European Commission

4.1.3 Comparison of EU, North America and Japan policies

The safety level in the railway system is generally high in Europe, North America and Japan. However railway accidents still arise in these countries and these accidents may have great impact in the confidence the public has in the railway as a transport mode.

In this context, each of these countries has put into place a legal, structural and organisational framework in order to maintain, promote and improve the rail safety. Safety policy on the railways of
Europe is under development today. It cannot be created by simply amalgamating existing national safety policies and regulations.

SAMNET document [Ref 35] “D1.2.1: E.Lemaire and L.Tordai “Report on comparison of safety policies” SAMNET/INRETS/ELM/WP1.2/D1.2.1/V4, 22/09/2005, analyses these various safety policies and gives a number of recommendations and compares the planned European framework approach in respect to railway safety management, against north American and Japanese ones as expressed in their policies and recommendations. This document also analyses more specifically the legal, structural and organisational framework in order to support rail safety, as it is mentioned in the regulations.

Harmonisation of the rail framework is one of the main objectives. This harmonisation puts into place a common culture in rail enhancing understanding of the approach used by various actors. This has a good impact on rail safety. The frameworks for safety policy used in these countries contain more or less the same items:

- A clear establishment of the responsibilities for:
  - The railway companies that have to express a set of internal rules proving their compliance to national and federal laws, regulations and rules. One of the major points is the formalisation of the responsibilities of the railway companies in their part of the system in a "Safety Management System" document that expresses how the company reaches all the safety requirements.
  - The national safety authority especially in safety that has the responsibilities of enforcing the laws, regulations and rules, monitoring the safety certification of railway companies and checking that all the stated requirements are met by railway companies.
  - An accident/incident investigation body that has the responsibility of conducting an independent inquiry into specific rail incidents and accidents.

- A process for safety certification of railway companies that involves the railway companies and the railway safety authorities.

- A process for incident and accident investigation that involves railway companies (RU, IM), the national safety authority and all relevant parties that may have an interest in the conclusions of the inquiry.

Europe is still a particular case as the European Union is composed of different Member States with their own safety culture. In this situation, the need for harmonisation is great and the European Railway Safety Directive includes harmonisation at European level of the safety indicators, methods and targets to obtain a common European rail safety culture without forgetting the specificity of each member state. As a part of the harmonisation the above items have been developed to get a harmonised rail safety framework. The Safety Directive is a compromise between all Members States that seems to achieve a global agreement of each rail player in Europe. However, by comparing the American and Japanese framework to the European one, it appears that some items of the European Railway Safety Directive may cause some different interpretations or misunderstanding or cause problems in the future.

It should be noted that the UIC Safety Platform have produced documentation on the issue of Shared Risk (see Position 3 below) and are working with representatives from the National Safety Authorities (NSAs) in respect to the issue outlined in Position Nº 4 below.
### 4.1.4 Comments and positions

**Position 1**  
*Safety and security aspects are closely linked and should be highlighted. The relationship between these aspects should be integrated in the Safety Management Systems*"  

This relationship should only apply where there is the potential for a direct link with system safety. Border security for example is not included.

**Position 2**  
*There should be coordination between Infrastructure Managers and Railway Undertakings in respect to their SMS. A minimum number of requirements must be defined so that the SMS of an RU is compatible with that of an IM (and vice versa) as far as the management of interfaces is concerned*  

**Position 3**  
*The procedure to resolve any discrepancies or disagreement between an Infrastructure Manager and a Railway Undertaking on their respective SMS must be developed. The UIC Safety Platform are in the process of preparing a paper in this regard.*

**Position 4**  
*In respect to certification, once the limit of validity of the certificate (five years) has been exceeded, the certification renewal process can be based on the differences between the previous and the new conditions (including SMS)*

### 4.2 Safety management system development

A safety management system (SMS) is an organisation’s formal arrangement, through the provision of policies, resources and processes, to ensure the safety of its work activity. An effective SMS helps the organisation to identify and manage risks efficiently. It allows an organisation to demonstrate its capability in achieving its safety objectives and in meeting regulatory requirements.

A crucial aspect of RU’s and IM’s safety management activity will be the management of interfaces. In many member state railways, the new organisational structure will increase the number of interfaces, and hence introduce potentially new types of risk. An organisation faces essentially three different types of risk to its operations:

- Internal risks, i.e. those associated with activities and locations for which the organisation is solely and wholly responsible.
- External risks, i.e. those originating from systems, people or organisations and processes that are wholly outside the scope of the organisation’s control.
- Shared risks, i.e. risks associated with activities or locations for which there are shared responsibilities rather than sole ownership; to manage such risks the organisations have to ensure that compatible approaches are used.

#### 4.2.1 Safety Management System proposed structure

The SAMRAIL project used the existing safety management practices of the member state railways and the experiences of other safety critical sectors (such as the civil aviation, maritime, nuclear and chemical sectors) [Ref 54] as the baseline information for the production of the SMS structure and framework [Ref 55].

The approach is described in document [Ref 55] D2.2.2: “Guidelines for Safety Management System”, SAMRAIL/SM/D2.2.2/V3.0, May 2004. It has been undertaken to develop a mature, practical approach to managing safety. It is particularly important that stable safety practices are used.
in order to ensure that migration to a common SMS approach will be smooth (avoiding major upheaval, such as drastic changes to operating practices) and cost effective. The diagram of Figure 3 shows the proposed elements of the SMS divided into a planning and risk control system and a learning system, in order to emphasise the dynamic nature of a good SMS. This organisation of SMS structure should be refined at Stakeholders level.

The Proposed Guideline [Figure 3] for the Safety Management System is based on the Deming Cycle. However, because of our chosen basis, i.e. the existing SMS of the EU railways, we had to expand and elaborate different stages of PDCA (Plan, Do, Check, act) in a slightly different way than can be found in typical quality or environmental management system standards. To best of our knowledge the proposed guideline covers all the stages of the PDCA cycle, and contains some specific elements known to be critical to railway safety management, e.g. Incident and Accident reporting and safety communication. In fact, the structure used in the guideline is compliant with the PDCA cycle and comparable to those used in OHSAS 18001, ISO9001 and ISO14001.

The following table shows these relationships.

<table>
<thead>
<tr>
<th>Risk planning and control system</th>
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<tr>
<td>1) Nature and Scope of Duty Holder’s Business</td>
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<td>2) Safety Policy</td>
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<tr>
<td>3) Organisational structure and Responsibilities</td>
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<tr>
<td>4) Competence, Training and Fitness</td>
</tr>
<tr>
<td>5) Risk Management</td>
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<tr>
<td>6) Safety Assurance</td>
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<tr>
<td>7) Emergency Management</td>
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<tr>
<td>8) Safety Communication and Information Integrity</td>
</tr>
<tr>
<td>9) Management of Rules and Standards, including Compliance</td>
</tr>
<tr>
<td>Learning system</td>
</tr>
<tr>
<td>10) Incident and Accident Reporting and Learning</td>
</tr>
<tr>
<td>11) Monitoring, Auditing, Corrective Measures and Annual Reports</td>
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</tbody>
</table>

Figure 3: The proposed elements of a Safety Management System

4.2.2 Safety directive and SAMRAIL SMS elements

<table>
<thead>
<tr>
<th>The basic elements of the safety management system required by the safety directive</th>
<th>Relevant elements from the proposed SMS framework</th>
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</thead>
<tbody>
<tr>
<td>(a) A Safety Policy approved by the organisation’s chief executive and communicated to all staff</td>
<td>1) Nature and Scope of Duty Holder’s Business</td>
</tr>
<tr>
<td></td>
<td>2) Safety Policy</td>
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<tr>
<td>(b) Qualitative and quantitative corporate targets for the maintenance and enhancement of safety and plans for reaching the targets;</td>
<td>5) Risk Management</td>
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The basic elements of the safety management system required by the safety directive

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<tr>
<th>Element</th>
<th>Relevant elements from the proposed SMS framework</th>
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<tr>
<td>(c) Procedures to meet existing, new and altered technical and operational standards laid down in TSI or in national rules referred to in Article 7 and Annex II or in other relevant rules and procedures to assure compliance with the standards throughout the life-cycle of equipment and operations;</td>
<td>10) Management of rules and standards, including compliance</td>
</tr>
</tbody>
</table>
| (d) Procedures and methods to carry out risk evaluation and implement risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations; | 5) Risk Management
|                                                                        | 6) Safety assurance                                                                    |
| (e) Provision of programmes for training of staff and systems to ensure that the staff’s competence is maintained and tasks carried out accordingly; | 3) Organisational structure and Responsibilities
|                                                                        | 4) Competence, Training and Fitness                                                    |
| (f) Arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure; | 9) Safety communication and information integrity |
| (g) Procedures and formats for how safety information shall be documented and designation of procedure for configuration control of vital safety information; |                                                |
| (h) Procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken; | 7) Incident and accident reporting and learning |
| (i) Provision of plans for action and alert and information in case of emergency, agreed upon with the appropriate public authorities; | 8) Emergency management |
| (j) Provisions for recurrent internal auditing of the SMS.               | 11) Monitoring, audit, corrective measures and annual report                           |


Concern has been expressed by a number of SAMNET partners that within the Safety Directive, there is a lack of clarity in respect to the exact scope of a Safety Management System (SMS). Their view is that an SMS is the complete suite of controls, standards, instructions etc., plus the organisational structure in place to support the acceptably safe operation of an IM or RU wherever they operate.

Many commentators appear to also use the term “SMS” to mean the description constructed by an IM or RU to support its application for authorisation or certification. It is recommended that an unambiguous new term is created and adopted to describe this application document.
The triangle shown in figure 4 represents a pictorial image of two phases. See also the positions in clause §6.1.5.

Figure 4: SMS Triangle describing the relationship between the application phase and the supporting documents making up the total SMS

4.2.3 Comments and positions

Position 5 Safety Management Systems while all having the same basic components; will differ from organisation to organisation depending on the size, organisation and type of services and operation.

Position 6 An organisation’s SMS should explain how the internal risks are managed, it should explain the approaches taken to minimise the external risks, and it should identify the shared risks and explain how they will be controlled through collaboration with others.

Position 7 A Common structure is needed for the high level application phase document that is presented for safety certification and authorisation.

Position 8 The SMS content should be compliant with the both Annexe III and Article 9 of the safety directive.

Position 9 The SMS could be a component part of a global or integrated management system including quality, environment and OHS as well as safety.

Position 10 The SMS should show the evidence of both its structure and implementation in practice that can be easily assessed by the safety authority
4.3 Harmonisation of operational rules and impact of OPE TSI

This section is intended for the purposes of investigating the effects of the OPE TSI for the conventional railway system (CR) as referred to within the framework of Directive 2001/16/EC.


The following are the main findings of this deliverable.

The TSI is a “Technical Specification for Interoperability” required by European Directive 2001/16. It sets out to define the requirements necessary to facilitate the operation of trains on the Trans European Networks providing detail on essential issues for interoperability by specifying the “what” and “who” but not the “how”.

The successful implementation of interoperability requires proper ownership by all the players concerned of the new rules, tools and working methods deriving from this regulatory framework. Also, employers are required to take into account the safety of their personnel in the new organisations and to encourage improvements in the safety of workers at work. Interoperability must therefore also be examined from the perspective of the future players, in order to prepare the relevant rules, tools and methods so as to ensure that the corresponding system functions efficiently and safely and is to a certain extent “future proof”.

On the other hand TSIs and Directives are parts of a harmonisation process of transport liberalisation on an international scale.

The main goal is to secure a position between international rules within established organisations and national rules, which often seek to protect domestic markets. Whilst the main objective of the international rules is to facilitate trade and commerce, they often fail to take sufficient account of key environmental protection and safety.

The Traffic Operation and Management subsystem is a structural subsystem according to Directive 2001/16/EC. However, the individual elements are closely aligned with the operational procedures and processes required from an Infrastructure Manager or Railway Undertaking for the granting of a safety authorisation/certificate under the terms of the Directive 2004/49/EC. Therefore, verification against the OPE TSI shall be the responsibility of the Safety Authority of each Member State concerned.

The relevant Member State shall carry out an assessment of any new or amended operational procedures and processes, prior to implementation, before granting a new or revised safety authorisation/certificate. This assessment shall be a part of the process for granting the safety certificate / authorisation.

The Infrastructure Manager or Railway Undertaking concerned must supply the Member State with appropriate documentation describing the new or amended operations processes.

Whilst the TSI describes the “what” and not the “how” on the EU rail network, it should be noted that some elements will still need to be covered by national rules. This is unavoidable because of the differences in national operation and technically related safety rules, culture and practice including language as well. The interoperability of a Europe-wide railway system is influenced mainly by the differences in operating rules, procedures and technical differences between infrastructure and in philosophy based on cultural and language diversities. Where there is an overlap between national rules and the TSI, the TSI takes precedence.
The objective of the OPE TSI is to set out the basic requirements for interoperability, initially across the TENs but eventually across all the lines of the European rail network. This certainly does not undermine the use of other agreements (e.g. RIV, RIC, OPW) or technical leaflets of UIC needed for the operation.

It must be remembered that the OPE TSI is not at present a rulebook and only sets out the high level requirements.

In principle it does not set out ‘how’ an activity will be undertaken. It does however, describe ‘what’ requires to be done and ‘who’ has the lead responsibility to define the final arrangements in connection with national requirements.

4.3.1 Effects of CR OPE TSI on SMS

The European Commission white paper “Transport policy for 2010: a time to decide” [Ref 8] points out that revitalising this sector means competition between the railway companies themselves. The arrival of new railway companies could help to bolster competition and should be accompanied by measures to encourage company restructuring that takes account of social aspects and work conditions.

This opening of the markets must be accompanied by further harmonisation in the field of interoperability and safety. Railway Undertakings must have freedom to decide how to operate their services, subject only to valid technical and safety limitations.

The TSI for conventional rail services and the Safety Directive are principal contributors to this process.

The Operational TSI for conventional rail describes objects to be certified on member state (European) level while the SMS describes how these certified objects should be managed within a given management organisation (at IM and RU level).

The main effect of the TSI on a typical SMS is to give the framework to establish an SMS by setting out the main European technical values, technological requirements and rules to be applied at all levels of the regulatory structure (national and local levels).

The SD requires that levels of railway safety must be maintained and “where reasonably practicable”, continuously improved.

The main complexities of this objective are caused by the interfaces between subsystems. It is complicated to properly treat the interfaces with just the Operations TSIs as it limits itself to describing high level requirements. There is an impact between the requirements within the TSI and the requirements for parts of the railway Safety Management System of RUs and IMs. These TSI elements have a direct influence, amongst other issues, on the requirements to obtain a safety certificate.

The TSI specifies requirements at a European level necessary for safety and interoperability. It leaves Member States the responsibility, in liaison with the EC, to specify relevant requirements at a national level.

4.3.2 Relationship between TSI and the SMS

The Operations TSI deals with amongst other things, the operating rules for traincrew, rules of train preparation and operation. It also deals with communicational aspects as well as staff competencies and medical requirements.

The SMS deals with Safety policy, safety targets, TSI/National Standards, training, competence of train staff, train staff to meet basic standards requirements, fitness and health, risk evaluation, accident investigation, audit
It is clear that the main areas of the OPE TSI and a typical SMS from a safety point of view are not so far from each other but the approach of treating these areas is slightly different.

The OPE TSI level deals with an entire subsystem. The SMS on the other hand covers only a part of this subsystem in which the OPE TSI is a higher level compulsory framework never forgetting that the main goal of this interactive process is to maintain the existing safety levels of operations.

As far as CSTs are concerned, they are intended to define the safety levels “that must be at least reached by different parts of the railway system as a whole”. The demand is aimed directly at the Member States. CSTs will however, also pass on to railway companies via their SMS and be reflected in company-specific safety targets. The OPE TSI has an influence on CSTs as well by complementing the framework of the SD.

Existing safety management systems have applied standards for quality (e.g. ISO 9001, ISO19011), environment (e.g. ISO 1401), health and safety at work (e.g. OHS), safety for railway applications (e.g. EN 50126). This is supported by the OPE TSI to achieve more suitable interoperability operational requirements.

Railway operations depend intrinsically on long standing methods and the far ranging experience and motivation of individuals. Such experience is obviously a strength, but it is also a weakness if this knowledge is not documented to be ensured for the future. The OPE TSI general requirements of staff concerning competences on training and health are to notify and further harmonise this knowledge.

Safety culture (not mentioned in either the SD or TSIs) is a combination of values, standards and principles of acceptable behaviour. This is part of a company’s culture, which is of particular importance for a business such as a railway that operates a complex technical system in order to provide its service.

The safety culture is always the present expression of the current common modes of behaviour, which is determined both by the attitudes of the active persons and the structure.

For shaping and guaranteeing safety in parallel with the safety processes which produce the service provided, the personal responsibility of the individual members of staff, in which the safety culture is also evident, is of particular importance.

The effect of the TSI on safety culture is to bring safety cultures together through a steady migration to a harmonised state by good communication and bilateral or multilateral agreements.

### 4.3.3 Comments and positions

The TSI is an acknowledged step forward giving the framework of international rail traffic regulation at a European level and promoting the liberalisation process. Nevertheless there are some elements of the operational subsystem for which the TSI permits wider flexibility on the use of national regulations, rules. These are mainly not at Member State level but on an operational and national coordination level. Based on the functional specification of subsystem we tried to identify these areas; gaps to be covered mainly by using national rules.

These are the areas to be harmonised further in order to increase the global effectiveness of regulations at an international level.

The identification process focuses mainly on activities which need human factor contribution or organisational changes and not on areas where technical investment is necessary to increase the level of harmonisation.
Position 11 **Comment** - the TSI states that the Member State is responsible for authorising the Infrastructure Manager or certificating a Railway Undertaking to implement the relevant elements of its Traffic Operation and Management System. The TSI recommends that this could be achieved in conjunction with, if not at the same time as, the granting of the Safety Authorisation or Safety Certificate required by Directive 2004/49/EC.

Position 12 **Comment** - one of the main goals of the TSI is to identify the responsibilities between RUs and IMs concentrating on human factors and processes.

Position 13 **Comment** – the TSI describes a series of Basic Parameters and defines the “target” for the operational sub-system of the future.

Position 14 According to the OPE TSI for conventional railways in conjunction with directives 2004/49, the responsibility for the train rests with the RU and the IM is responsible for the infrastructure. The method by which they discharge their responsibilities and how they coordinate these with each other should be described in their SMS.

Position 15 The management of interfaces is something that must be dealt with at the operational level (RU-IM, IM-IM and RU-RU). Nevertheless the OPE TSI through the functional and technical specification of the operations subsystems supports the identification of the responsibilities of IMs and RUs. This is a holistic system approach to be carried out at national level, which is supported by OPE TSI as a framework and using the best practices available.

a) We note that in the staff related specification area, the OPE TSI does not consider all staff categories but only those dealing directly with the train operation and the movement of the trains (train preparation staff, drivers etc) relevant to the interoperable interface. We further note that vehicle maintenance staff are not included as it is understood that this activity is felt to be entirely within the activity of the RU and not a direct interface that affects interoperability. We recommend that these staff be taken into account in a further step of TSI development.

Position 16 It is noted that the common medical requirements related to in Chapter 4.7 of the OPE TSI are only relevant to the staff categories described in the TSI. It is recommended that these requirements are reviewed within the near future to ensure that they continue to be relevant and that they are widened to include the staff categories that will be included in the future.

Position 17 Communication (formalised communication) needs a continual harmonisation process related to the language requirements of cross border staff or drivers operating on two or more national networks. We note that the OPE TSI makes it clear that the minimum requirement of formalised communication is not sufficient to cover all possible situation especially on cross border operation and that it only a basis upon which to construct a protocol.

Another area is the role of the rulebook and route book. Although the OPE TSI provides a general framework concerning the main requirements, the content of these books should be further harmonised in order to improve the common understanding of requirements. This would be a step forward to promote harmonising of safety culture as well.
Position 18  We would further comment that train braking remains a train related specification to be resolved. We recognise that considerable steps have been taken to resolve this “open point” and that until resolution is achieved bilateral and multilateral agreements will continue to be developed, accepted and used.

Position 19  The requirements in respect to the method of indicating the rear of a train whilst harmonised in the High Speed OPE system remain to be harmonised within the Conventional system, especially in respect to freight trains. After the OPE TSI has been published initial interoperability will need to be through bilateral or multilateral agreements until a more harmonised position is developed.

Position 20  The rules on communication between the key players are an important issue. The importance of human factors is increasing through using the European wide interoperability requirements in railway operation. We recommend that this domain should be more harmonised and regulated in a future version of the OPE TSI.

Whilst we consider that this is essentially a matter for the ERA to manage in a future passage of their work we recognise that the linguistics project jointly being developed between the UIC and the CER seeks to improve the existing OPE TSI requirements in this area.
4.4 Occupational Safety Policies

The SAMNET document [Ref 40] D1.3.1: L.Tordai, G.Gavrila and E.M.El Koursi “Report on Comparison of Occupational Safety Policies” SAMNET/ERRI/GG/ WP1.3/D1.3.1/V0, 8/08/2005 compares the occupational safety approach of different national practices with the relevant EU Directives related to railway safety management. It should be noted that whilst the EU railway directives describe the players involved in railway safety management, a harmonised safety management structure and the responsibilities of each player within it, they make no special provisions related to occupational safety.

In respect to occupational safety, the Council of the European Communities issued Directive 89/391/EEC with the main objective of introducing measures to encourage improvements in the safety and health of all workers at work. It also contains general principles concerning the prevention of occupational risk, the protection of safety and health, the elimination of risk and accident factors.

Article 6 establishes the general obligations of an employer:

“Within the context of his responsibilities, the employer shall take the measures necessary for the safety and health protection of workers, including prevention of occupational risk and provision of information and training, as well as provision of necessary organisation and means. Without prejudice to the other provisions of this Directive, where several undertakings share a work place, the employers shall cooperate in implementing the safety, health and occupational hygiene provisions and, taking into account the nature of the activities, shall coordinate their actions in matters of the protection and prevention of occupational risks, and shall inform one another and their respective workers and/or workers' representatives of these risks”.

The directive applies to workers in the fields of road, rail, air, sea and water-way transport.

The general provisions concerning improvements in the health and safety of workers (framework Directive 89/391/EEC) are fully applicable to the new EU directives concerning railway safety aspects.

4.4.1 OHSAS 18001 – A Specification for OHS Management Systems

A more general OHS management system standard for all companies is provided by OHSAS 18001.

In 1996, BS 8800 “Guide to occupational health and safety management systems” was published as a British standard. The result of the harmonisation of the different existing specifications resulted in the development of the Occupational Health and Safety Assessment Series (OHSAS), the OHSAS 18001.

An occupational safety policy is intended to create a healthy and safe environment for the railway staff working in the railway transport chain.

Safety policies may differ depending on the safety culture of a given country, but the importance of OHS is universally recognised, whether it is integrated into a safety management system or is implemented as a separate organisational activity.

The cross-sector nature of Occupational Health and Safety (OHS) concerns all CEN Technical Committees, which prepare standards with OHS consideration.
4.4.2 OHS Forum

An OHS Sector Forum was created in order to improve the safety and health working conditions through standardisation by coordinating OHS issues in the CEN system (CEN Technical Board, sectors, CEN Technical Committees) and with its partners (CENELEC, European Telecommunications Standards Institute (ETSI), European industry, Social partners and ISO).

The UIC Occupational Safety Group is also actively engaged in this domain and as been for a number of years. With a broad cross section of IMs and RUs, it was spawned as a body charged with following up the recommendations made during the occupational Health and Safety Conference in 1996. In order to obtain more information on the state of the art concerning management of health and safety, a benchmark [Ref 108] “Benchmark study on safety management in 36 European railways, UIC – Occupational Safety Group, Utrecht, Oslo, Paris 2000.” study amongst 36 European railways was performed.

The final conclusions of the benchmark study include the following:

- The railways are engaged in a process of major development and have the ambition to implement management systems.
- The striving to combine occupational health and safety management with either quality management or the management of environmental care (generally) points to a need to structure OHS management to existing models and experience in this area. These findings substantiate the view that the method used should follow the guidelines conforming with EN ISO 14001 on environmental care.

In parallel with this benchmark study, the UIC established a set of guiding principles in 1999 for developing a management system for health and safety at work within the railway companies. These guiding principles provide advice on ways of developing and improving management systems for health and safety at work within the railway companies. They are primarily targeted at executive level personnel who seeking to improve the performance of their companies, but also provide support for staff and specialists acting as advisors to management. These guiding principles propose a progressive approach to developing a model, accompanied by criteria for a management system on health and safety at work.

4.4.3 Comments and positions

Position 21 Comment - the employer must ensure that employees' workplaces comply with the minimum requirements for health and safety as set out in Annex II (89/391/EEC), Part A, with effect from 31 December 1994.

Position 22 Comment - based on the examination of various occupational safety approaches, it can be stated that Occupational Health and Safety (OHS) should be managed at the same level of importance, whether integrated or excluded from the Safety Management System (SMS).
It is important to give equal treatment to the technological and human aspects of the railway system. There should be no difference in the approach to safety between train operating activities and technological functions, or between human beings, whether employees or passengers.

The SMS that integrates OHS presents a more systematic approach and therefore suggests a more equal treatment of passengers and employees, whatever their role in the railway transport system. The integration of OHS into the SMS can be justified by the examples from the Netherlands, Eurotunnel and Canada.

Whilst accepting that an equal approach should be afforded to these issues, we would further comment that any such integration should be limited to those issues that affect the safety of the operational railway system.

It is clear that no single railway undertaking or infrastructure manager has the necessary and global feedback to explore and control all hazards. There is a need to share experience on accident and incident investigations and to encourage transparency of data in order to develop a common approach to health and safety.

To this end it should be noted that the Occupational Safety Group of the UIC Safety Platform is engaged on this particular aspect and remains essentially the principle railway sector working in this domain.

4.5 Cost Benefit Analysis on safety measures as a method


For the creation of a single European rail transport market it is important to increase confidence between the players in the market and between Member States. For this purpose the EU Safety Directive introduces a mechanism to adopt a minimum CST expressed in risk acceptance criteria for individuals and for society. Different targets could be valid for different parts of the rail system (such as the high-speed system, the conventional rail system or lines dedicated to freight traffic). The resulting safety targets will describe the minimum safety level, so that member states could apply more demanding targets, for example for infrastructure, as long as they do not impose requirements above CST on railway undertakings.

In order to assess if CSTs are met, CSMs will also be developed. The CSMs could harmonise the use of independent safety assessors for checking compliance with essential requirements or for assessing conformity with requirements of safety certificates. CSMs have to describe how the safety level and the achievement of safety targets and compliance with other safety requirements are assessed by defining and developing:

- risk evaluation and assessment methods,
- methods for assessing conformity with requirements in safety certificates and safety authorisations and
- methods to check that the structural sub-systems are operated and maintained in accordance with the relevant essential requirements.
A CBA is a systematic approach to estimate the costs and benefits of different safety measures and could be an assessment criterion of CSMs as described in the Safety Directive.

The Safety Directive aims to set up an agreed procedure for CSMs to estimate the financial effect of CSTs. This procedure is needed to verify whether a safety measure or safety improvement is reasonably practicable.

“Member States shall ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Community legislation and technical and scientific progress and giving priority to the prevention of serious accidents.”

Based on the prescriptions of the Safety Directive, an economic analysis of safety measures or safety consequences of technical and organisational developments is unavoidable. Even if the method of analysis is slightly different, the main goal remains the same: to support the decision-making process and maintain or increase the safety level of sub-systems or of the whole system.

The analysis of a proposed safety measure results in a set of estimates of each of the five components of a typical CBA. There are in practice three levels at which these estimates may be applied:

- **Level 1**, where the results are used to contribute to a purely **subjective** judgement. Each of the components of costs and consequences are considered separately, making an analysis of costs and consequences and attributing values to them.

- **Level 2**, where the safety and cost results are combined to estimate the **relative** ranking of a set of possible measures. The aim is to calculate a single number that indicates the amount of additional safety that is achieved and divide this by the total cost. The cost-effectiveness of different safety measures may then be compared and put in order. This ensures that the railway achieves the highest level of safety from a finite budget.

- **Level 3**, where all of the consequences are expressed in financial terms and combined to provide an **absolute** estimate of the value of a measure. It is possible to calculate an absolute estimate of whether a safety measure is justified if a financial value is attributed to safety consequences. Some countries use a *value of preventing a fatality* to convert the statistical number of equivalent fatalities that are saved or lost into a monetary equivalent. The absolute value of the proposed measure is found by subtracting the net financial cost from the value of the safety benefits.

The UIC Safety Platform has identified five CBA components in their report (Cost Benefit Analysis [Ref 114). The first is the cost. The others are the four types of consequences – financial, safety, environmental and system. These consequences can be quantified if there is an agreed financial value for a service. There are well-established techniques that measure “willingness to pay” to estimate the value of time saved or lost. A simpler alternative might be to assume that the value is equal to the fraction of total capacity lost or gained, divided by the total cost of the railway.

### 4.5.1 Economic aspects of using the EU Safety Directive & TSIs

In the traffic and operations environment, one aspect that traverses almost all disciplines is railway safety. All disciplines have to take into consideration that implementation of different traffic safety measures may have other effects than just the positive effect of reducing the risk of being killed; these include increased travel time, inconveniences, environmental impact and impact on the system as a whole. The main goal of an economic case study is to identify the degree of optimisation in the relationship between increased efficiency resulting from improved safety and the increase in costs induced by the measure undertaken.
“Vision Zero” can be the underlying principle of a traffic safety policy based on the ethical principle: “One must always do everything in one’s power to prevent death or serious injury”. Nevertheless, the acceptance of a certain level of risk can be accepted, based mainly on economic arguments.

The EU Safety Directive and the TSIs for operations provide a broad framework for using national rules in order to support the prescriptions of the SD and the TSIs. Activities on developing the economic aspects of using the SD or the TSIs are in progress: case studies are increasingly revealing the economic consequences attached to safety in the light of technical developments or the results of safety measures focusing on sub-systems or parts of the railway system (e.g. upgraded lines or new lines including more sub-systems).

The Operational TSI is not at present a rule book and only sets out the high level requirements. Nevertheless the OPE TSI has a very important and not insignificant potential for economic impact which should be harnessed in the rules harmonisation process (technical and organisational consequences of using the OPE TSIs).

Economics means one thing to the specialist and another to the general public. When people hear the word “economics”, they think it has to do with the management of money.

In the case of safety, economics means more: How can better safety conditions be made profitable for business?

Certainly, the role of safety in business management, its financial costs and benefits, is an important aspect of economic analysis, but it does not exhaust the topic. A system (e.g. a railway system or sub-system) could be modelled using the main component of the system and the effects of these components when producing services. A train running on a given line is a form of service for passengers or freight when using system or sub-system elements and human resources to complete these activities.

In most cases the cost-benefit analysis is made when system (or sub-system) development occurs (technical, organisational, etc.) in terms of costs, with special reference to safety measures.

The OPE TSI takes into account the relationship with safety by giving a number of high level regulations. The economic effect of using the OPE TSI is to be elaborated at Member State level and at IM and RU level. The method to evaluate this effect should be harmonised or at least that part which is national or the part affected by bilateral or multilateral agreements between the member states for interoperable services. The OPE TSI together with the Safety Directive steers European railway safety regulation towards stronger analysis of cost and benefit and explicit substantive decision-making rules.

### 4.5.2 Economic Aspects of Safety Management

Safety is a decisive and very important factor in the increasing mobility of railway transport. The economics of safety is to identify and qualify the economic consequences of varying reliability. According to an American slogan, *Money lost to accidents, is money wasted*. Certainly, the role of safety, its financial costs and benefits, in business management is an important aspect of economic analysis, but it does not exhaust the topic. In addition, economists generally assume that all decisions are made in a “rational” manner, where rationality has a very specific meaning.

From an economic point of view, the economic aspects of this procedure cannot be separated from each other: all elements should be part of the economics of safety measures and part of business economics. Therefore, the cost-benefit analysis uses the same main elements for the calculation to provide alternatives for decision-makers.
There is an optimum investment level in railway safety. If this investment level is insufficient, there is a risk that more accidents will be the result. If however, the total cost for safety is too high, there is a risk that the price of tickets will increase and, consequently, clients could shift to other modes of transport, mainly to road transport – increasing overall the potential risk to society. The figure below shows how this optimum can be identified in a given situation:

![Figure 5: Safety cost and accident cost](image)

This optimum [Figure 5 should be balanced against the safety target. When increasing safety, the cost of safety increases exponentially, while the risk is an asymptote to zero.

### 4.5.3 Comments and positions

The balance between the RAMS performance of a system and the costs of development and ownership of the system is well reflected by lifecycle costs. The system lifecycle is a sequence of phases, each containing tasks, covering the total life of a system, from initial concept through to decommissioning and disposal. The lifecycle provides a structure for planning, managing, controlling and monitoring all aspects of a system, including RAMS, as the system progresses through the phases, in order to deliver the right product at the right price within the agreed timescales and at an appropriate safety level.

The economic aspect of the Safety Management System and Interoperability is a very important domain representing the business thinking relating also to the safety aspects in the reorganisation process of the European Railways. Although the railway system is the safest system within the transportation domain, it needs to be changed in a business-oriented way, making it more attractive on the transport market. Nevertheless, this restructuring of the railways should be managed in a cost-effective way to include technical developments and the safety aspects of SMS.

**Position 23** From a safety point of view, all costs affecting safety, including the consequences of incidents or accidents, should be taken into consideration. In all cases this means the direct and indirect costs caused by an accident or incident or forecast with a given probability. Both costs have to be identified and used in the calculation.

**Position 24** The SMS and the safety aspects of technical developments should correspond to an LCC performance according to EN 50126.

**Position 25** European railway organisations are in the process of implementing their SMS. Nevertheless, with regards to the economic aspect of safety measures, a common method for cost-benefits analysis using a harmonised cost structure should be applied in each case of development undertaken in the technical or organisational domain.

It should be noted that the UIC Safety Platform have published papers on all these issues [Ref 114].
5 Common Safety Targets; Indicators and Methods issues

5.1 CST (Common Safety Targets)


This section summarises the results of this deliverable and the results of the dedicated workshops on CSMs, CSIs and CSTs. It further presents the current position that SAMRAIL/SAMNET have reached with the development of CSTs, referring to source documentation for fuller explanations where appropriate.

CSTs mean the safety levels that must be reached by the different parts of the rail system (such as conventional rail system, high speed rail system, long railway tunnels or lines solely used for freight transport) and the system as a whole, expressed in risk acceptance criteria”.

5.1.1 Deliberations on the Definition of the CSTs

According to article 7.4 of the Safety Directive, CSTs shall define the safety levels that must at least be reached by different parts of the railway system and by the system as a whole in each Member State, expressed in risk acceptance criteria for:

a/ Individual risks relating to:

- Passengers
- Staff including the staff of contractors
- Level crossing users and others,
- And, without prejudice existing national and international liability rules, individual risks relating to unauthorised persons on railway premises

b/ Societal risks

CSTs can refer to different “groups at risk” such as passengers, staff, track workers etc. Besides these groups a distinction can be made between individual risk and collective or societal risk.

Individual risk defines the chance of a person dying due do to a certain activity. This is most often expressed in the chance of a fatality per year. Individual risk is measured in terms of the chance of a fatality per individual per year.

Societal risk deals with the consequences of a railway accident on the environment (in terms of harm and damage). For instance, accidents with several fatalities have a greater impact on society than accidents with one or two fatalities. Societal risk can be expressed in group risk which refers to the acceptability of accidents with several fatalities. A definition of societal risk is still to be agreed.

According to Art 7.4, the Directive requires at least five different Global Safety Targets that must be reached in each Member State. These correspond to:

- Global individual risk for passengers
- Global individual risk for staff
- Global individual risk for level crossing users and others
Global individual risk for unauthorised persons on railway premises

The ERA will phase the introduction of CSTs in two stages over the course of seven years after the Safety Directive came into force in April 2004. The first stage over a period of five years will initially involve only determining the status quo and defining targets to ensure that safety levels are maintained. The second set of targets will then be aimed at improving safety levels. However, such improvement must be seen in the context of the reference to Article 4, which requires the Member States to generally maintain railway safety and to continuously improve it "where reasonably practicable".

In accordance with the current legal situation, when defining targets, there is a risk of exposing the railway system that is already one of the safest modes of transport to a government-imposed industry-specific safety spiral. The targets and their associated indicators should be comparable to the safety level of other modes of transport. If, for example, the risk acceptance criteria are defined as average values at European level and they are regularly revised and adapted to technical advances, then they should not continue to spiral upwards with no upper limit, but should take an asymptotic approach to a generally accepted level.

The Safety Directive gives very little information about the content of the CSTs. What is certain is that CSTs should define a safety level and must take the form of risk acceptance criteria, i.e. they must detail the risks that are considered acceptable for individuals or society. The questions as to whether they should be qualitative or quantitative targets or both and how the concept of societal risks is to be understood remain unanswered.

- Possible qualitative targets can be defined:
  - to ensure safe operation through sufficient legal requirements
  - to implement proactive measures for risk reduction where necessary for ethical, social, legal or economic reasons
  - to use suitable methods applied in other safety-critical industries, e.g. selection tests

- Possible quantitative targets can be defined:
  - numerically quantifiable individually and socially acceptable existing risks at various system levels, e.g. annual reduction of shunting accidents
  - subsystem dependent risk acceptability criteria, e.g. through comparison with the existing risk level
  - safety performance of other modes of transport, e.g. fewer deaths per passenger

5.1.2 General / Global CSTs and Specific CSTs:

Commonality for targets could therefore be considered only as applicable to objects which are to the same in all of the Member States such as generic functions, sub-systems, operations or part thereof which are characteristic of all area of the European rail system. Safety targets applied to requirements in TSIs, sub systems or Interoperability Constituents are good examples of such Specific Common Safety Targets. The main question concerns the level at which the Specific CSTs should be defined.

Deriving acceptable risk levels for the various parts of the railway system requires first a classification of all the risks into various categories, and then the assignment of a target or acceptable
risk level to each category with respect to each group(s) exposed to the risk (see also Global CSTs). Such a process is also called **risk apportionment**.

There are several ways of classifying risks depending on their various characteristics. Based on the investigations it can identify roughly 5 distinct approaches for the classification of risks and derivation of acceptable risk levels for parts of the railway system:

- System breakdown approach
- Breakdown by categories of hazard causes
- Functional breakdown approach
- Breakdown by hazard types
- Breakdown by accident types

These 5 approaches (5 possible structures for Specific CSTs) correspond in fact to different levels of detail that can be focused on when analysing safety of a railway system. This can be illustrated by the following figure showing the hierarchy in a typical safety requirement allocation process:

![Figure 6: proposed apportionment of safety targets](image)

This figure is inspired by CENELEC EN: 50129 (used for signalling system), and shows the relationship existing on the one hand between a hazard and the accidents it could lead to and on the other hand the relationships between the functions/processes protecting against the hazard and the constituents (technical sub-systems, procedures or human operators) implementing these functions.

At the very bottom it is shown that it would be in theory possible to allocate safety responsibilities between IM and RU at the end of the process.

### 5.1.3 Functional breakdown approach for CST apportionment

Simply put, the functional breakdown approach uses the railway architecture [Ref 74] developed by the AEIF, which is a functional system analysis of a conventional railway system covering the full chain of railway transport. This analysis represents a systematic and coherent decomposition of functions up to four levels. Next the hazards and ensuing accidents related to each function must be identified and quantified if accident statistical data is available.
This new method was presented to the Commission, DG TREN, during the first quarter 2002 and to the Members States Committee (A21C) in April 2002.

The AEIF emphasised that no existing method can demonstrate totally the completeness of the BP (Basic Parameters) and the interfaces against safety, even if similar methods can increase the confidence in them. A system is constituted by a set of functions that are executed by tasks and supported by the architecture (hardware and software). The tasks are influenced and characterised by several modes and configurations. In fact, the tasks will be carried out in relation to the current mode and the operational context. The architecture is organised into sets of “devices” assigned to the tasks and in close relation with available resources. The system itself works in various operational contexts (strategic, control and management) requiring an adaptation of the resources required to discharge the functions.

For example, the functions are supported by the resources. For each function, at least one resource has to be allocated to it. Reciprocally each resource supports at least one function, otherwise this resources is useless. Moreover, the resources support the function with the parameters of the resources and the functional requirements of the function.

For example, the rail and the wheel (products) interface will certainly inherit additional constraints on their respective geometry, because of the functional requirement of track guidance associated to the function “To guide and carry the train” that they support. In other words, rails having a given geometry and wheels with a suitable profile will guarantee the track guidance conditions needed to guide the train. These dependencies will port significant assistance in the validation of parameters.

Following the structure of Directive 2001/16/ EC, the conventional rail system is decomposed in 6 subsystems:

- Infrastructure
- Energy
- Control command and signalling
- Traffic operation and management
- Rolling stock
- Telematic applications for passenger and freight services.

The described functional analysis methodology is applied on all of these subsystems. These subsystems are performed by a number of functions, which are implemented by a number of resources and programmes. All these elements constitute the Representative Architecture of the conventional rail system.

At the first level of the decomposition, 17 functions have been identified (Table 13). The second and the third level of the functions breakdown can then be detailed in further steps.
Table 13: Conventional rail functions.

For the first two functional levels, the link with the sub-systems (e.g. operations) is defined via the basic parameters (table 14).

Table 14: Functional decomposition of railway system.
This approach showed that if some functions can clearly be allocated to the IM or to the RU, responsibilities within other functions are shared. The shared responsibility aspect of some functions may derive from the goal of the function that involves both the IM and the RU or from the way it is implemented. Ensuring safe railway operations can also be expressed in a qualitative way. Both qualitative and quantitative safety targets can be allocated from a bottom-up approach as well as a top-down approach.

A global CST is expressed as a risk (i.e. a combination of frequency and severity of harmful events). This implies that the specific CST should also be expressed as a risk, namely as a portion of the global residual risk. What would however be most useful for operators and suppliers alike is to know what should be the acceptable frequency rate of events such as an accident, a hazard, and more importantly, a function fault, a constituent dangerous failure, etc., so as to determine specific safety requirements on parts of the railway system, particularly for new systems. Thus it is important to stress that whichever way the risks might be apportioned for defining CSTs, there will still be some rather complicated safety allocation process necessary behind in order to derive (qualitative and quantitative) safety requirements.

5.1.4 Comments and positions

SAMNET has concluded that it is difficult to apportion risk between different parts of a system. Risk apportionment raises serious ethical problems, such as the suggestion that the level of safety should be different for different types of service (e.g. high-speed or local services). Common apportionment is especially difficult when the national networks vary so greatly. Risk apportionment does make sense between physical subsystems for which a SIL value may be defined. However, most of the risk on the railway arises from failures of the Safety Management System and other human factors and not from failures of physical sub-systems.

Position 26 All deliberations on the definition of targets must be based on an analysis of the ratio between cost and benefits taking into account political, social and economic commensurability.

Position 27 Global CSTs are the reference to derive CSTs for the various parts of the railway system because the specific acceptable risk levels should be derived for these different parts of the railway system as well as for the global safety targets. This suggests an apportionment of global safety targets to specific parts of the railway system although we would stress that this should not become a method that is adopted too generally.

Position 28 Use global CSTs to meet more closely the requirements of the safety directive for CSTs.

The possible top-down approaches considered in SAMRAIL deliverable "D2.4.1 An approach for acceptable risk levels and risk apportionment strategies for European railways" will not be re-explained, and the conclusion of the report, ie that a top-down approach does not lead so far to any conclusive specific CSTs, is accepted as a general rule. This obviously does not preclude further work on the subject based for instance on a functional breakdown. The top-down approach is mostly used for deriving Specific Quantitative Safety Targets.
5.1.4.1 Use hazard identification and risk analysis to obtain specific CSTs

Hazard identification and risk analysis are a good way to set safety targets for functions or systems. This is basically the route chosen by the current European norms as explained in §3.3.2.3 or in SAMRAIL deliverable "D2.4 Acceptable Risk Level" [10]. Using methodology described in SAMRAIL deliverable "D2.3.2: Common methods risk analysis" [11] such as PHA (Preliminary Hazard Analysis), it is possible to trace specific functions or systems contribution to hazardous situations and hence allocate specific safety targets.

5.1.4.2 Specific common safety targets

Position 29 Specific CSTs could be considered together with related specific CSIs as the latter could provide feedback on the effectiveness of the barriers.

Were suitable specific CSIs to become available, they could in turn provide the basis for decisions on future specific CSTs. At present the effectiveness of the barriers can only be interpolated from a more general evaluation of operations. Failures of the barriers do not always result in hazards or incidents. Following on from the implementation of SMS, specific elements or processes in the internal audits could however be included to monitor the effectiveness of the barriers together with more formal systems for monitoring near-misses and minor incidents.

It is therefore recommended that the bottom-up approach should be explored further but starting from specific cases.

Position 30 The development of specific targets should start from Specific Safety Targets existing in some member states, which could be harmonised to become Specific Common Safety Targets. It should be noted that in this respect we consider that the use of the word “common” refers to something that is recognised or accepted, rather than harmonised – the more popular interpretation of the word common.

Position 31 The Common safety targets are for the NSA to supervise the system safety level. Targets are also necessary at TSI level to facilitate acceptance of innovative product.

Position 32 Stakeholders such as RUs, IM and manufacturers, will have to set their own (corporate) targets in coordination with their key interfaces and the principle players. These stakeholders will still be required to take any CSTs set at national level into account.

Position 33 Comment - when setting safety targets it is important to recognise that safety emerges as a consequence of many elements of the rail system, including but not restricted to: the issue of the safety certificate or safety authorisation, approval for the introduction of new equipment and national rules. Targets must be aligned with the elements of the railway that needs to be improved to achieve them.

Position 34 Comment - apply the Safety Directive requirements to develop Global safety targets.

Position 35 We recommend the use of the AEIF breakdown structure to manage the iceberg effect of setting targets at Member State level. Whilst we recognise that the AEIF functional breakdown is something that Member States have endorsed as a tool at Article 21 level, we believe that a review should be conducted to establish whether it is complete and exhaustive and if it would benefit from complementary elements.
It is necessary to consider when setting the targets and developing the plans that the number of measures that can actually be implemented within a particular period of time will, however, be limited as every company can only provide a certain budget for the implementation of safety strategies. From all the potentially realisable proposals, the company must therefore make a selection on the basis of the ratio of cost to benefits. In that process, the aspects of reasonable practicability cited above – economic viability, customer needs and social demands – are determinants for the railway companies. In addition to the financial condition of an affordable safety level, which does not threaten the existence of the company, social aspects, market needs and the possibility of image enhancement resulting from safety will be part of the measures’ benefits taken into account for the selection.

Specific Common Safety Targets will be useful only if data is available to assess the safety of a particular interoperable function or subsystem in order to decide on its feasibility strictly from a safety point of view and to support the development of risk assessment.

5.2 CSI (Common Safety Indicators)

5.2.1 Relationship between CSTs and CSIs

As the Safety Directive is aiming to set Common Safety target (CST) for monitoring safety performance, it is essential that an agreed set of Common Safety Indicators (CSIs) be used to ensure that measured safety performance (the effectiveness of Safety Management System) of different organisations are comparable and are related to CSTs. Each of these safety targets would need to be defined with adequate Common Safety Indicators (CSIs). The SAMNET deliverable [Ref 37] “D1.2.3: L.Tordai “Common Safety Targets and Common Safety Indicators” SAMNET/UIC/TOR/WP1.2/D1.2.3/V1, 06/2005” describes the elements needed to develop common safety indicators. This section summarises the results of this deliverable and the results of the dedicated workshop on CSMs, CSIs and CSTs.

<table>
<thead>
<tr>
<th>Global target</th>
<th>Indicator (for one Member State, per year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of death or injury to passengers from any causes</td>
<td>Total number of deaths and of injuries on railway premises from any causes (per passenger km) this would include falls on station platforms, accidents due to passenger behaviour etc</td>
</tr>
<tr>
<td>Risk of death or injury to railway employees</td>
<td>Total number of deaths and of injuries (per track km); includes staff employed by contractors</td>
</tr>
<tr>
<td>Risk of death or injury to innocent third parties</td>
<td>Total number of deaths and of injuries (per train km); includes harm to persons correctly using level crossings or living near the railway</td>
</tr>
<tr>
<td>Risk of death or injury to illegitimately present third parties</td>
<td>Total number of deaths and of injuries (per train km); includes trespassers and persons using level crossings incorrectly and causing the accident</td>
</tr>
</tbody>
</table>

Table 15: Individual Global safety targets and Indicators.

Missing from the above tables is a definition for societal risk. A consistent, unique definition should be established. Until this is resolved it is proposed to use the following indicator (see table 16) for this type of risk:

<table>
<thead>
<tr>
<th>General (consequence) target</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collective catastrophic risk of death or injury for people outside railway system boundaries</td>
<td>Total number of deaths and of injuries (per year) due to railway accidents affecting large groups of population outside the railway boundaries</td>
</tr>
</tbody>
</table>

Table 16: Societal Global safety targets and Indicators.
This risk is expressed as a collective risk and not an individual risk, and is meant to essentially include risks of catastrophic accidents involving people and the environment, for example the release of dangerous goods. Since these events ought to be extremely rare, it is considered that a factor for scaling would not be necessary, therefore a unit per year for each country is suggested.

5.2.2 Comments and positions

It is proposed to use Global CSTs and Specific CSTs related to identified parts of the railway system. CSTs should be defined within an overall goal that provides a framework for safety decisions. One or more corresponding Common Safety Indicators (CSIs) can measure the level to be achieved by Member States.

General Indicators: measure the overall level of safety of the railway within a Member State.

Specific Indicators: measure the effectiveness of the SMS of individual companies (RU & IM). The safety level of the whole system must be reached by different parts of the system. Firstly the performance of the whole system and the effectiveness of Safety Management System should be measured.

Position 36 Definition of separate sets of CSIs for general and specific part of the railway.

Position 37 The societal risk should have a defined definition and common agreement before using it.

Societal risk proposed by SAMNET should contain:

- Risks that affect society as a whole, such as environmental harm. This is in addition to the total risk of harm to groups such as individual passengers, staff, level crossing users and unauthorised persons,
- Risks to persons living near the railway (railway neighbours),
- Risks of collective accidents, that is of accidents causing multiple fatalities,
- Intermodal effects, for example the fact that passengers will transfer to road because they perceive the railway to be unsafe,
- The risk that the public will lose trust in the institutions of the State.

Position 38 Finally, concerning suicide, it is proposed to treat this category separate from other safety indicators. Moreover, imposing a common indicator for suicide seems outside the scope of the Safety Directive, although were this to change, an indicator for suicide could be easily accommodated.

Position 39 The harmonisation of terminologies of different parameters and examination of data consistency using for CSIs is unavoidable. Especially a common agreement needed for the definition of serious injuries.

Position 40 It is suggested to use fatality data until there is a consensus on how to define and measure injuries. Serious injuries have a great importance in measuring safety performance and therefore should be included into the safety measuring process.

Position 41 Specific targets and specific indicators should be based on frequency of occurrence of critical events that might have resulted in an accident. They should apply to the more
frequent and serious critical events (e.g. SPAD). The Specific CSIs should be monitor the
effectiveness of SMS.

**Position 42** Need of Global Indicators first then see if there is a need of Specific Indicators

**Position 43** Indicators should be aligned with targets; we should be developing the indicators that we have.

**Position 44** It is recognised that an accident and incident database is needed to support the development of CSIs.

The UIC database exists so should be further developed and utilised as a source for this workstream,
It is recognised that Member States and the ERA will be obliged to draw their information from other sources such as Eurostat.

**Position 45** Indicators about direct financial costs of accidents are of no use for the purpose of developing CSIs

**Position 46** Indicators of management of safety should be done by external audits that are comparable and consistent, e.g. ERA to supervise the accreditation and standards of the auditors.

<table>
<thead>
<tr>
<th>General Common Safety Target</th>
<th>General Common Safety Indicator (for one Member State, per year)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Position 47</strong> Risk of death or serious injury to passengers as a result of train operations or who are harmed by any other means</td>
<td><strong>Position 48</strong> Total number of deaths and of serious injuries on railway premises as a result of train operations or who are harmed by any other means (possibly scaled as “per passenger km”) - this would include falls on station platforms, accidents due to passenger behaviour etc</td>
</tr>
<tr>
<td><strong>Position 49</strong> Risk of death or serious injury to railway employees.</td>
<td><strong>Position 50</strong> Total number of deaths and of serious injuries (per track km); includes staff employed by contractors</td>
</tr>
<tr>
<td></td>
<td>It may be effective to separate track workers and on-train staffs. “Track km” may be the correct scaling parameter for track workers but it is unlikely to be correct for on-board workers</td>
</tr>
<tr>
<td><strong>Position 51</strong> Risk of death or serious injury to third parties (innocent or illegitimately present)</td>
<td><strong>Position 52</strong> Total number of deaths and of injuries (per train km); includes harm to persons correctly using level crossings or living near the railway. This should also include trespassers and persons using level crossings incorrectly and contributing to the cause of the accident</td>
</tr>
<tr>
<td></td>
<td>In adopting these positions, it should be noted that in practice it is often not possible to identify innocent and culpable third parties. Care will need to be exercised by Member State to ensure a satisfactory way is developed for determining into which category each victim should be placed.</td>
</tr>
</tbody>
</table>

*Table 17: Positions on Global safety targets and Indicators*
The CSI related to the total number of deaths and of injuries (per train km); including harm to persons correctly using level crossings or living near the railway takes into account the trespassers and persons using level crossings incorrectly and contributing to the cause of the accident. This position merges the safety targets related to the risk of death or injury to innocent third parties and the risk of death or injury to illegitimately present third parties.

It is necessary to specify how the global target levels relate to individual safety targets of an organisation (RU or IM). It is assumed that the main task of RU & IM, in this regard, will be to collect the relevant data related to the safety of their operation, e.g. safety indicators and associated precursors, and from these draw statistical inference about the safety level of their operation. This will require a degree of risk assessment as data output will not be sufficient to determine the risk of high severity, low probability events. A consensus is needed with regard to the following:

- A common set of individual safety targets for RU and IM
- Relationship between individual and global targets
- Common criteria for identifying safety indicators and precursors for individual safety targets
- Common procedure for determining the safety level from these data
5.3 CSM (Common Safety Methods)

According to the European Safety Directive the Common Safety Methods (CSMs) are the methods to be developed to assess whether safety targets and other safety requirements are met. Typical CSMs shall comprise methods for:

- Risk evaluation and assessment;
- Assessing conformity with requirements in safety certificates and safety authorisations (issued in accordance with the Articles of the directive), and;
- Checking that the structural subsystems of the trans-European high-speed and conventional rail systems are operated and maintained in accordance with the relevant essential requirements (as far as they are not yet covered by TSIs).

The SAMNET deliverable [Ref 41] “D1.3.2: G.Bearfield et al “Common Safety Methods Position Paper”, SAMNET/ATKINS/BEAR/WP1.3/D1.3.2/V2.0, 11/07/2005” describes the elements needed to develop Common Safety Methods. This section summarises the results of this deliverable and the results of the dedicated workshops on CSMs, CSIs and CSTs. This section presents the current position that SAMRAIL/SAMNET have reached with the development of CSMs, referring to source documentation for fuller explanations where appropriate.

It focuses on the CSM for Risk Evaluation and Assessment, as this is both a priority in the Safety Directive and the area where most previous activity has been focussed. SAMRAIL [Ref 56] and SAMNET [Ref 41] established a common framework for application of safety methods. It consists of:

- System Definition
- Identification of Hazards
- Risk Analysis
- Risk Evaluation
- Risk Reduction
- Risk Control
- Risk Monitoring
- Risk evaluation and assessment

The urgent priority in the Safety Directive is for the development of a CSM to address risk evaluation and assessment. A literal interpretation of the Safety Directive implies that the CSM for risk evaluation and assessment includes just a method for assessing the risk associated with the railway system, and comparing those against a set of defined risk criteria (i.e. System Definition, Identification of Hazards, Risk Analysis and Risk Evaluation). ‘Risk Evaluation and Assessment’ must support the development of an organisation’s safety requirements and the procedures that comprise the SMS.

However, it is important to stress that the separation between CSMs in the directive is arbitrary. An integrated approach to analysing risk and managing safety through the use of CSIs, CSMs, CSTs and a robust SMS is what is actually required.

Position 53 The generic CSM framework for risk management consists of: System Definition, Identification of Hazards, Evaluating the risks, Risk Analysis, developing the control measures, implementing the controls and monitoring effectiveness. We have to be careful with terminology. The scope of a risk must be clearly defined (quantitatively if possible,
qualitatively if not) before deciding if it is acceptable. We have therefore assumed that, when the Directive refers to Risk Evaluation and Assessment, it is using the word “Evaluation” to mean the first process (literally estimating the value or level of the risk) and assessment for the second stage (assessing what action is needed).

**Position 54** The generic CSM framework for assessing conformity with the typical elements that may be required when safety certificates and safety authorisations are issued in accordance with Articles 10 and 11 of the directive, consist of, amongst others, Risk Reduction, Risk Control and Risk Monitoring.

### 5.3.1 Commonality required in application of the CSM for risk evaluation and assessment

There is an inherent difficulty in allowing a variety of tools and techniques to be applied for risk analysis and assessment, and yet also wanting to obtain results from the application of these various methods that are comparable across various organisations, and various member states. It is therefore important to establish the degree of commonality that is actually required between member states in the application of the CSMs. There are three key principles that need to be able to be met, to enable comparisons to be made:

1. **Commonality of the System Definition.** The System Definition activity provides the scope of all subsequent risk identification, analysis and management activity. The description should then be translated into sets of functional models which describe and represent the sub-system functionality. This is to provide a suitably detailed set of models for subsequent risk analysis. The Work Package (WP) 2.3 framework suggests the use of the Structured Analysis and Design Technique (SADT) technique [Ref 73] for building these functional models.

2. **Commonality of Conceptual Model used to undertake Risk Assessment.** The bow-tie concept [Figure 7] is the generally accepted conceptual model used to structure risk analysis and assessment. There are various tools and techniques that can be used to elaborate this conceptual model and undertake more detailed risk analysis depending on the depth of analysis required and the nature of the accident and its various causes.

   It is important to determine:
   - when risk assessment is required;
   - of what type;
   - to what scope and
   - to what depth of analysis.

   A mechanism or process is needed within the CSMs to allow such decisions to be made in a consistent and auditable way.

Risk Assessment can be used for different purposes. Where entirely new systems or processes are being implemented then a detailed risk assessment is required in order to establish that the safety requirements are necessary and sufficient (as was undertaken for the Woippy-Mannheim case study).
This analysis would generally be undertaken at the design stage; i.e. when such changes were being planned and designed.

**Position 56** It is important to determine: when risk assessment is required; of what type; to what scope and to what depth of analysis.

(3) **Commonality of Base Units of Risk.** ‘Risk’ is accepted to be the product of the probability of occurrence of an accident and the severity of that accident. However there are various and different approaches adopted across each member state for quantifying risk and a number of units of risk used. If the base units for risk are standardised (such as SI units of Risk) then the results of any analysis should ultimately be comparable. Establishing common base units of risk is therefore a key area of concern in establishing a common and comparable approach to risk assessment and safety management.

**Position 57** Hazard identification based on a common list of scenarios used as a check list at the minimum should be compulsory. The Eurosig list provides a good basis for such a list of common scenarios.

Initial use of the techniques indicates that the Eurosig scenarios provide a good basis for analysis. However, the Eurosig events can be quite ‘general’ and it may be necessary to refine some (e.g. the event "Driver error of judgement" is not precise enough to give the real cause of failure). Such refinement of events will therefore depend on the system boundary and also on the nature of the organisation. However the event itself will remain useful for example it may be used as the basis of discussions between companies, especially for cross-border operations.

Any accident scenario under analysis can be considered as a series of coincident events. The ‘bow-tie’ method is proposed as a useful way to represent and analyse the scenarios. The ‘knot’ of the bow-tie is the hazard being analysed. ‘Barriers’ represent the technical and operational measures that prevent events in the accident scenario from occurring, and hence reduce accident risk.

The ‘bow-tie’ model is not a tool or technique for risk analysis. It represents the underlying mental model used by most safety engineers to undertake risk analysis. The majority of risk analysis tools and techniques develop and formalise this representation in one way or another.
• The probability of occurrence of the hazard
• The subsequent likelihood of occurrence of possible accidents
• The consequences of each possible accident.

For detailed analysis, calculation will involve estimation of the likelihood of occurrence of each of the events in the accident scenario, possibly involving fault and event tree type models. Where less detailed risk analysis is required, a qualitative Risk Matrix approach is discussed and presented for ranking the risk of hazards. The appropriate safety method to apply to further analyse the likelihood of occurrence of an event, will depend on what type of occurrence the event is (e.g. human error, hardware failure, software failure etc).

In the document [Ref 41], safety tools and techniques and how to match their use to activities that comprise the risk assessment CSM, technical system boundaries and railway system lifecycle phases are presented.

Position 58 As long as the risk analysis is undertaken using recognised safety engineering tools and techniques and that decisions are clearly traced, there is no need to impose common tools for undertaking risk analysis. However, guidance should be provided to confirm which techniques are acceptable and how they should be applied.

Position 59 In order to facilitate cross-acceptance, the quality of the risk analysis process should be monitored and controlled.

For example, there should be:
- requirements for the competence of staff who carry out the risk analysis;
- clearly defined process activities identifying entry and exit criteria and
- an auditable process whose quality of application can be determined with associated process metrics.

The company may use any method of evaluation that:
- is accepted by the national safety authority that awarded its safety certificate or safety authorisation
- takes account of all possible hazardous events that may result from the change and the consequences of those hazardous events
- considers degraded modes of operation, multiple levels of safety management and the role of humans in the management of safety.

The company should adopt a systematic framework for risk assessment that is accepted by the national safety authority that awarded its safety certificate or safety authorisation and which, at a minimum, provides documented evidence of:
- the difference in the level of risk
- the factors that have been considered when deciding that the change is acceptable
- the reasons why the company believes that it is acceptable
- the actions that the company will take to manage the risks of the change
A method of evaluation or a framework for risk assessment shall only be considered to be accepted by a national safety authority if it defines the circumstances under which it is applicable, how it is to be used and the competence of the persons who use it.

5.3.1.1 Risk Evaluation

Once the risks associated with the various hazards have been calculated it is necessary to evaluate their acceptability. The tolerability of calculated risks should be evaluated against the CSTs derived for the project.

The table below extracted from SAMNET deliverable [Ref 41] “D1.3.2: G.Bearfield et al “Common Safety Methods Position Paper”, SAMNET/ATKINS/BEAR/ WP1.3/D1.3.2/V2.0, 11/07/2005” shows the annual reporting indicators proposed for each member state. The safety directive and the document propose that the Common Safety Targets should be specified as a level of ‘individual’ risk.

<table>
<thead>
<tr>
<th>Global Target</th>
<th>Indicator (for each Member State, per year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of death or injury to passengers from any causes</td>
<td>Total number of deaths and of injuries on railway premises from any causes (per passenger reference unit) this would include falls on station platforms, accidents due to passenger behaviour etc</td>
</tr>
<tr>
<td>Risk of death or injury to railway employees</td>
<td>Total number of deaths and of injuries (per employee reference unit); includes staff employed by contractors</td>
</tr>
<tr>
<td>Risk of death or injury to innocent third parties</td>
<td>Total number of deaths and of injuries (per population reference unit); includes harm to persons correctly using level crossings or living near the railway</td>
</tr>
<tr>
<td>Risk of death or injury to illegitimately present third parties</td>
<td>Total number of deaths and of injuries (per population reference unit); includes trespassers and persons using level crossings incorrectly and causing the accident.</td>
</tr>
</tbody>
</table>

Table 18: List of individual risks for global CSTs.

Position 60 The total number of deaths and injuries should be weighted against some agreed criteria such as ‘equivalent fatalities’. The ‘equivalent fatalities’ would represent an aggregation of ‘fatalities’ and ‘major’ injuries according to a ratio yet to be decided (e.g. 1 fatality = 10 major injuries = 1 equivalent fatality).

Care must be exercised in arriving at this weighting formula as the term “Equivalent fatalities” can be misunderstood because it implies that, for example, 10 broken arms are “equivalent” to a death. They are clearly not equivalent but some weighting of this form is needed for quantitative analysis. An alternative might be to consider adopting the term “Fatalities and Weighted Injuries” instead of “Equivalent Fatalities”.

The current proposal is that minor injuries would not be included in the measures, as they tend to indicate risk associated with low severity accidents.

The CSTs will be allocated to various system functions of the railway according to the AEIF functional breakdown [Ref: [Ref 74]]. The functional breakdown of the railway is generic, and independent of the particular technology used to implement functions in each organisation or in each member state. Therefore it was concluded that CSTs broken down in this way will be more translatable between organisations and member states.
Position 61  Acceptability of risk should be based on ensuring that at least the same level of safety performance is maintained AND every reasonably practicable improvement has been made before the change is implemented.

Position 62  There must be agreed and standardised risk units and risk criteria so that the performance of Railway Undertakings and Infrastructure Managers can be compared across all member states. All risk measures should be consistent with or transferable to, these units.

It is necessary to specify how the global target levels relate to individual safety targets of an organisation (RU or IM). It is assumed that the main task of an RU or an IM in this regard, will be to collect the relevant data related to the safety of their operation. A consensus is needed with regard to the following:

- A common set of individual safety targets for RU and IM
- Relationship between individual and global targets
- Common criteria for identifying safety indicators and precursors for individual safety targets
- Common procedure for determining the safety level from these data

There is little support (in terms of tools and techniques) for establishing how an organisation meets its overall safety targets (See 5.3.3). Once the CSM process to follow has been agreed tools and techniques will need to be developed to help RUs and IMs to routinely apply the criteria and procedures for ensuring that they meet their organisational safety targets.

5.3.2 CSMs for meeting safety requirements

The CSMs for meeting safety requirements are related to:

- Defined in the safety certificate of each RU
- Defined in the safety authorisation for each IM
- Derived for structural sub-systems not completely covered by TSIs

CSMs are required for ensuring that the various safety requirements put in place by an organisation are routinely and continually met by the organisation. This CSM should comprise of the risk reduction, risk control and risk monitoring stages of the risk assessment process as outlined by SAMRAIL.

This section describes a risk reduction strategy. In the first instance, hazards should be eliminated where possible. If they cannot be eliminated then their frequency should be reduced. Finally, the system design should ensure that the consequences of any remaining hazards are mitigated.

5.3.2.1 Risk Reduction

The possible approaches to risk reduction stated in the output from WP2.3.3 are:

- Revision of the technical system design
- Modification of operational procedures
- Changes to staffing arrangements
- Training of personnel to cope with the hazard
These risk reduction approaches essentially describe revisions that an organisation can easily make to its safety requirements. They all occur at the ‘design’ phase of the organisation in that they relate to ensuring that the correct procedural and technical requirements are theoretically in place to reduce risk to an acceptable level. Understanding which technical and procedural requirements are safety-related, and to what degree are critical and their importance to safety in the organisation can be understood.

5.3.2.2 Risk Control and Monitoring

Risk Control and Monitoring is about how an organisation understands the practical effectiveness of the safety requirements. The organisation must monitor all of its barriers to ensure that failures or weaknesses in the barriers are identified and rectified before an accident actually occurs. The barriers in an organisation are its safety requirements. Each different type of barrier should be monitored using a different process. For example, where the safety requirements are operational procedures they can be controlled and monitored using safety inspections, and auditing. Where the safety requirements are functional system requirements they can be monitored by inspection or they may also have diagnostic functions which aid in understanding where safety requirements are no longer being met or are ineffective.

Position 63 Risk Reduction, Control and Monitoring are considered to be part of the CSM for assessing conformity with requirements in safety certificates and safety authorisations (as they concern the achievement of risk levels rather than their assessment).

A common tool to assist risk reduction and control is the use of a Hazard Log. This involves recording all identified hazards and actions which mitigate risk in the Hazard Log. The Hazard Log is then a ‘live’ document used for recording identified hazards, the assessed risk and recommending appropriate changes to reduce the risk. Such changes should be considered and implemented under a change control system. The Hazard Log is made available to all personnel working on the project.

The directive mentions ‘Safety Targets’, ‘Safety Regulations’ and Safety Requirements’. It is important that we differentiate between these three different things.

5.3.3 Review of existing principles and techniques, including those from standards

The main standard in use across the European Community, which describes risk and reliability assessment, is EN50126 – ‘Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)’. The standard gives examples of some risk acceptance principles and defines a comprehensive set of tasks for the different phases of a generic lifecycle for a total rail system. However, EN50126 has evolved from the perspective of adopting new systems to the railway environment (e.g. a new interlocking, or new rolling stock).

This is subtly different to the focus of the safety directive, which is putting in place, demonstrating and maintaining a risk-based safety management system for an organisation (the RU or IM).

5.3.4 Comments and positions

Position 64 All of the techniques described in CENELEC standards 50126 are potentially relevant and usable for CSMs.

Position 65 Need of ‘application guidance’ for CSMs that should not be a repetition of existing detailed guidance like that which exists for the CENELEC standard EN50126. It should include clear criteria that need to be met when applying each CSM.
Any guidance on CSMs should include a description of the circumstances under which each CSM should be applied by each stakeholder (RU’s and IM’s in particular) and also the degree of detail to which the CSM should be applied. Where CSMs suggest the use of existing techniques (e.g. for Risk Evaluation and Assessment) then existing standards can be referenced. It was stressed that the Application guidance would need to clarify the responsibilities for applying CSMs and outline what criteria each party needs to meet in applying CSMs. This should include clear criteria that need to be met when applying each CSM.

This is particularly important for Safety Authorities to determine what their criteria for assessment are. It also allows clear contractual relationships to be drawn up between organisations – equipment and service suppliers in particular will need to know how the CSMs affect their work.

**Position 66  CSMs will be needed to justify technical, operational or organisational changes.**

CSMs should not just undertake Risk Assessment in response to change (NB Substantial Change refers to a need to notify the safety authority and is not an indicator of whether CSMs should be applied); they should also assess if targets and safety requirements are being met. Therefore as the result of audit findings or monitoring, some risk assessment of application of CSMs may result.

**Position 67  Global responsibility has to be clarified. The directive states that the RU is responsible for their activity and the IM are responsible for theirs and SA has the responsibility on behalf of the state.**

**Position 68  At the interfaces between organisations there will need to be some alignment of Safety Management Systems. It was agreed that a common framework was required for defining and managing organisational interfaces. This is necessary, as a large number of new interfaces will be created. (e.g. some IMs will interface with three or four hundred RUs).**
6 Cross - Acceptance

6.1 SMS Certification, Authorisation and Reporting Processes

The objective of this section is to describe the process for implementing the Safety Directive’s certification and authorisation requirements. The roles of the various stakeholder organisations within these processes are also defined.

This section also describes the products/deliverables to be developed to facilitate the processes and the requirements for transparency of these processes and products.

This section of the report describes the stakeholder organisations (also known as Duty Holders) involved in the processes for RU certification and IM authorisation (which are described in Section 6.1.1) and the responsibilities of these stakeholders with regard to these processes.


The actors include the following:

- **Infrastructure Manager**: Any body or undertaking that is responsible for establishing and maintaining railway infrastructure which may also include the management of infrastructure control and safety systems. Current IMs in the EU are companies like Network Rail in the UK, ProRail in the Netherlands, RFF in France and departments within national railway organisations such as DB.

- **Railway Undertaking**: Any public or private undertaking licensed according to applicable community legislation, the principle business of which is to provide services for the transport of goods and/or passengers by rail with a requirement that the undertaking must ensure traction; Businesses referred to as ‘Train Operating Companies’ in the UK and Netherlands are typical examples of RUs.

- **Safety Authority**: the national body entrusted with the tasks regarding railway safety in accordance with this directive (e.g. the (former) UK HSE, or EBA in Germany) or any bi-national body entrusted by member states with these tasks in order to ensure a unified safety regime for specialised cross border infrastructures (e.g. Channel Tunnel Safety Authority).

- **European Railway Agency**: the Community agency for railway safety and interoperability established by 221/2004/EC directive

6.1.1 SMS Certification and Authorisation Processes

Each RU and IM is required to implement a formal Safety Management System. The Safety Management System is required to be structured in accordance with the framework provided in Section 2.1.3. Detailed guidance on the implementation and maintenance of the proposed SMS framework is provided in the document [Ref 55].

In order to be granted access to a Member State’s railway infrastructure each RU is required to obtain safety certification from the relevant safety authority.
Safety Certification is in two parts:

- The first part of the certification process (Part 1) is confirmation of the safety authority’s acceptance of the RUs SMS, in compliance with the Safety Directive.
- The second part of the certification (Part 2) confirms acceptance of the RUs arrangements to meet the application specific elements of their operations (e.g. TSIs, national safety rules and so on).

The Safety Authority in the Member State where the RU first establishes its operation shall grant both parts of the certification – ‘Part 1’ and ‘Part 2’ – as described above.

The Safety Authority will provide detailed guidance on how to obtain the safety certificate. This guidance will list all requirements; national safety regulations, rules and standards and so on. Any further relevant documentation required will also be made available to the applicant.

Where a RU is seeking operation on an additional Member State’s railway, ‘Part 2’ level certification only will need to be sought from that Member State’s Safety Authority. This ‘Part 2’ level certification will be required from each Member State upon whose infrastructure the RU seeks to operate.

The ‘Part 1’ aspect of certification should be transferable between Member states. A RU’s safety certificate must be renewed, at the latest, every five years after the initial certification by the Safety Authority. This renewal process may involve several safety authorities, where a RU has multiple ‘Part 2’ safety certifications.

Each national safety authority shall inform the European Railway Agency, within one month, of all safety certificates that it has issued, renewed, amended or revoked. The European Railway Agency will maintain a public register of all undertaking certifications.

**RU safety certification**

![Diagram of safety certification process for Railway Undertakings](image-url)

*Figure 8: Safety certification process for Railway Undertakings*
6.1.1.1 Safety Authorisation of Infrastructure Managers

In order to be allowed to manage and operate rail infrastructure, the IM is required to obtain safety authorisation from the relevant safety authority (in other words, the safety authority in the Member State in the infrastructure is located). The safety authorisation will need to comprise:

- Authorisation confirming acceptance of the IMs safety management system in compliance with the Safety Directive, and the high level requirements detailed in this document.
- Authorisation confirming acceptance of the provisions of the infrastructure manager to meet specific requirements necessary for the safe design, maintenance and operation of the railway infrastructure including, where appropriate, the maintenance and operation of the traffic control and signalling system.

The IM’s safety authorisation must be renewed, at the latest, every five years after the initial authorisation by the Safety Authority.

It is the responsibility of the IM to inform the relevant safety authorities, without delay, in the event of any substantial changes to the infrastructure, signalling or energy supply or to the principles of its operation and maintenance. Update to the safety authorisation may be required in the event of any such changes.

If at any time a safety authority finds out that an IM no longer satisfies the conditions for a safety authorisation it shall revoke that authorisation, giving reasons for its decision. The safety authority may require that the safety certification be revised following substantial changes to the safety regulatory framework.

The Safety Authority shall inform the European Railway Agency within one month of the safety authorisations that have been issued, renewed, amended or revoked.

**IM Safety authorisation**

![Diagram of Safety Authorisation Information Flow for Infrastructure Managers]

**Figure 9: Safety Authorisation Information Flow for Infrastructure Managers**
6.1.2 Documentation Submission and Reporting Requirements

6.1.2.1 Railway Undertakings – Safety Certification Submission

A RU will need to make a submission to the relevant safety authority, prior to the commencement of operations or prior to continuation of operations after a period defined by the safety authority (which will be no greater than 5 years). The submission will need to be structured to facilitate ‘Part 1’ and ‘Part 2’ level approvals.

The ‘Part 1’ submission will focus on the SMS aspects that are generic and therefore are applicable to the RU’s operations regardless of the member state in which the operations are being undertaken. The SMS description produced should reference all of the safety processes and procedures which make up the SMS.

The ‘Part 2’ submission will focus on the network-specific aspects of the RUs arrangements for ensuring safety. This section of the submission will therefore detail the specific requirements in place concerning:

- Technical Specifications of Interoperability (TSIs);
- National safety rules;
- National technical standards including in particular those relating to compliance of rolling stock;
- National operational standards including those relating to management and competence assurance of staff;
- Relevant national legislation;
- Application of appropriate risk assessment techniques including identification of and adherence to risk control measures.

6.1.2.2 Infrastructure Manager - Safety Authorisation Submission

In order to achieve safety authorisation, evidence should be supplied to the safety authority. This evidence should comprise two parts.

The first part of the submission should provide evidence that the IM’s SMS is in place and is sufficiently robust for the organisation to effectively manage safety. The SMS description produced should reference all of the safety processes and procedures which make up the SMS.

The second part of the IM’s submission for Safety Authorisation should comprise the provisions of the infrastructure manager to meet specific requirements necessary for the safe design, maintenance and operation of the railway infrastructure including, where appropriate, the maintenance and operation of the traffic control and signalling system. These specific requirements will include:

- Technical Specifications of Interoperability (TSIs);
- National safety rules and national technical and operational standards;
- Relevant national legislation;
- Evidence of application of appropriate risk assessment techniques including identification of and adherence to risk control measures.
The relevant national safety authority will provide details of and guidance on meeting the pertinent specific requirements.

### 6.1.3 Audit by the Safety Authority

It is envisaged that the Safety Authority may undertake audit of IMs and RUs in order to ascertain the appropriateness of arrangements described and the rigour with which reported processes/procedures are applied and stated requirements met. Therefore the submissions of these duty holders should provide the Safety Authority with a rigorous and thorough documentation set on which to base any subsequent audit activity.

For example, in Norway they undertake RU audits every 2 or 3 years, and IM audits (in differing locations) more regularly. They intend to continue doing this even though this specific responsibility is not mandated in the Railway Safety Directive.

#### 6.1.3.1 Infrastructure and Railway Undertaking Annual Report

All IMs and RUs shall submit annual safety reports. These reports must be submitted to the relevant Safety Authority before 30th June in the year following the calendar year to which the report relates.

The safety report shall include:

- Information on how the organisations corporate safety targets are met;
- The results of planned safety activity;
- Development of national safety indicators;
- Use of Common Safety Indicators as they relate to the business activity of the reporting organisation;
- Evidence and results of internal auditing;
- Any deficiencies or weaknesses in respect to organisations, their operations and infrastructure that may have been identified.

#### 6.1.3.2 Safety Authority Annual Report

Each year the safety authority shall publish an annual report concerning its activities in the preceding year and send it to the Agency by 30 September at the latest. The report shall contain information on:

- The development of railway safety, including an aggregation at Member State level of the CSIs laid down in Annex I of the directive;
- Important changes in legislation and regulation concerning railway safety;
- The development of safety certification and safety authorisation;
- Results of and experience relating to the supervision of IMs and RUs.

The safety submissions of all RUs and IMs operating on the same member state railway are to be made freely available between these parties. This is deemed to be important as knowledge of the safety management systems of each of these parties is necessary to enable them to interface appropriately on a given member state railway.
6.1.4 Assessment method

This section aims at proposing a basic assessment process and minimum criteria to be used to assess the Safety Management System SMS described in the document [Ref 39] entitled D1.2.5: E.M.El Koursi “SMS assessment criteria, Position paper”, SAMNET/INRETS/ELK/WP1.2/D1.2.5/V1, May 30th 2005

It should be used as a starting point for developing the assessment process. It gives the basic elements for developing the assessment process in order to ensure that the necessary elements of an SMS are available and maintained for all aspects of system operation and are in accordance with standards, directives, TSIs and the requirements of the quality system (e.g. ISO 9000 series). It also aims at checking that the development activities and processes are operated in accordance with the SMS and that evidence is available to show the implementation of the SMS.

The assessment should be based on the verification that the RU or IM has the required safety management capability and an adequate SMS exits, is effectively implemented and demonstrates that safety objectives are met or will be met. The suggested basic criteria are based on safety directive requirements and the SAMRAIL document Guidelines for the Safety Management System GMA2-2001-52053 [Ref 55]

The objectives of the assessment activities are:

- To ensure that the necessary elements of an SMS are available and maintained for all aspects of system operation
- To ensure that the SMS elements are in accordance with standards directives and TSI and the requirements of the quality system,
- To ensure development activities and processes are operated in accordance with the SMS,
- To ensure evidence is available to show the implementation of the SMS.

The Assessment Plan and requirements will take into consideration the following information:

(a) The assessment basis, such as the standards, law, constraints and legal requirements,
(b) The assessment criteria which will form the basis of the assessment,
(c) The SMS elements to be assessed,
(d) The assessment activities to be undertaken,
(e) The team that will undertake the assessment,
(f) The responsibilities of the team,
(g) Methods, Tools and Techniques
(h) The minimum level of documentation to be examined,
(i) A schedule of assessment activities,
(j) Procedure for dealing with appeals, complaints and disputes.

The assessment report should provide detailed reasons why the SMS is accepted or rejected. The duty holder will have the opportunity to rectify the SMS against the issues raised. The number of iterations that may take place to arrive at a final decision (accepted SMS or rejected) can be agreed between the assessors and the duty holder.
The three elements to be assessed are:

(a) The **adequacy** of the SMS documentation:
   - Compliance with relevant standard and best practice
   - Fit for its intended purpose
   - Safety policy is translated into safety objectives and activities
   - Reference to risks having been identified and evaluated and controls applied
   - All relevant safety policies, procedures and documents are identified
   - Procedures for continuous improvement are specified

(b) The **effective** implementation of the SMS:
   - Compliance with SMS requirements checked
   - Resources assigned and their readiness checked
   - Audit process planned and applied
   - Relevant data identified, collected and analysed
   - Process for identifying gaps & weaknesses in SMS exists

(c) The **demonstration** that safety objectives are met regarding the expectations before and after operation commences.
   - All documentary evidence identified
   - Show how evidence prove that safety objectives are met

6.1.5 Comments and positions

The assessment process will be employed by many different organisations and common measures need to be in place to ensure consistency not just within member states but also across all member states. The assessments are likely to be carried out by teams under the direction of a lead assessor. Competence can therefore be aggregated if appropriate to ensure overall competence of the process.

**Position 69** As with the SMS being assessed, the performance of the assessment process should be monitored. The employment of a user group to periodically review the operation of the process should be mandated. Similarly an independent audit of the delivery of the assessment process will give confidence to stakeholders that it is being competently and safely managed.

Harmonised criteria are necessary to obtain the mutual recognition of the assessment results of SMS implementation.

The RU or IM shall provide all the evidence required to demonstrate compliance with the detailed criteria. The evidence should be organised and shall be readily available for audit, walk-through, review and detailed examination.

The assessment should be focused on the adequacy and effectiveness of the SMS.

Where necessary, single criterion can be broken down into several lower-level criteria and shall be used according to current best practice and experience. The assessor shall provide an assessment report
that summarises the approach, findings, criteria and provides detailed reasons why the elements of the SMS passed or failed the criteria.

Position 70  Documents produced for the purposes of Safety Reporting such as annual report are to be made publicly available. Details of certifications and authorisations issued by each Safety Authority are to be made publicly available in a register produced by the European Railway Agency.

Position 71  The assessment should be based on the verification that the RU or IM has the required safety management capability, an acceptable SMS exists, it is effectively implemented, and that it demonstrates that safety objectives would be met. The assessment of an existing SMS would give the opportunity to show that past objectives have been met.

Position 72  Phase one assessment is dedicated to the review of SMS documentation by checking the completeness and the consistency of the documentation and the evidence.

Position 73  The second phase of assessment can start dealing with the satisfactory implementation of SMS by checking how the procedures, policies, and manuals of practice have been implemented at the upper levels of management and at service levels.

Position 74  The competence of assessors in the topic being assessed and their ability to competently assess the item are important. We recommend that the ERA and their network of NSAs should develop a process that is available in the “public” domain – that is, available to the rail community.

Position 75  The assessment process should employ recognised good management practice, for example ISO 9000, 14000, OSHAS 18000 type processes.

Position 76  The assessment body should specify, in published criteria, the circumstances in which an SMS or portion of an SMS should be submitted for reassessment. It is essential that minimum criteria are consistent across all member states.

Position 77  The relationship between Part 1 and 2 of certification requires further underpinning.

The Safety Directive makes it clear that RU and IM must assess risks arising from their operations, and ensure that the outcome of the risk assessment is translated into appropriate risk controls. However, in contrast to a safety case regime such as the one previously used in the UK, there is no requirement in the Safety Directive for the duty holders to provide their risk assessments as evidence to their safety authority.

It is not clear who is responsible for examining the assessment in detail to assure that CSMs have been properly applied, appropriate risk controls are used and CSTs achieved. This suggests that a certificate or authorisation indicates that the safety authority is satisfied that the duty holder has the capability to control risks, but the responsibility for doing so and ensuring this rest with the duty holders, they alone are accountable for their safety performance.

More clarification is needed to ensure that each duty holder is in control of the system, equipment and staff in order to fulfil its responsibility. For example, IM needs to be responsible for accepting rolling stock on its network in consultation with the safety authority. It is not obvious whether it will have any roles in setting drivers competence and other train related standards.

Position 78  There should be a requirement to make applications open for public inspection
Position 79  There should be requirements to keep documentation, including audit reports, for set periods.

Position 80  A right of appeal from a decision to refuse or to revoke, a safety certificate or authorisation.

The conditional approval issue is not addressed in the Safety Directive. Depending extenuating circumstances, a safety authority may have to grant exemptions.

Position 81  Co-functioning and collaboration between IM and RUs is vital for maintaining safety levels of the overall system.

Although the IM is given an important role (see Article 9.3 of the Safety Directive), there is no explicit provisions for them to review the safety submissions of the RU seeking certificates for approval on their networks. Similarly, RUs should have the opportunity to comment on the safety management system of both the IM and of any RU that could affect their operation.

This is especially important in respect to the ability to understand and manage the risks at the safety-related interfaces between these organizations. Not only will this mean that the system is being coordinated as a intrinsic whole, we believe that this will also facilitate the certification/authorisation process if this collaborative approach can be demonstrated to the Safety Authority.

6.2 Cross acceptance of Vehicles under the Interoperability & Safety Directives

This section analyses the different scenarios that apply to the acceptance of vehicles intended for international operation (for example, new vehicles, existing vehicles required to traverse different routes, etc). The Interoperability & Safety Directives each contain various provisions that are intended to simplify and assist in the cross-acceptance of a vehicle and the safety management system of Railway Undertakings between Member States.

The approach is described in the document [Ref 44] entitled “D1.3.5: A. Stuparu and N. Duquenne “Cross Acceptance of Vehicles under the Interoperability & Safety Directives”, SAMNET/INRETS/AS/WP1.3/D1.3.5/V1.2, 24/06/2005. It is important that the acceptance process to be used for cross-acceptance of rail vehicles, and Railway Undertakings traversing international borders, is clear, pragmatic, requires the minimum of bureaucracy and paperwork, but above all will result in vehicles that:

- Are sufficiently safe, interoperable, and economical to build and operate,
- Are compatible with the rail infrastructure over which they operate
- Meet the legal requirements imposed by the Second Railway Package
- Capable of cross-acceptance in each Member State as efficiently and effectively as possible.

There are two elements of any process to accept a rail vehicle:

- Factors that will apply irrespective of the infrastructure over which it will operate (e.g. crash resistance, static gauge, braking efficiency, maximum speed and power demand, etc).
- Infrastructure dependent interaction (e.g. potential electromagnetic interference between vehicles and the signalling systems, radio systems, dynamic gauge, etc.).
6.2.1 Scenarios

There are 5 different types of cross acceptance scenarios for Rolling Stock, which have to be catered for as described below.

**Scenario A** - The Rolling Stock (RS) has been authorised by MS “A” as meeting the Essential Requirements defined in the relevant Interoperability Directive through compliance with the Rolling Stock TSI.

It is fully compliant with the National Specific Cases for rolling stock in the TSI for Member State “A”. It is now required to operate on a network in member state “B”.

For scenario A no further authorisation of the rolling stock by the Safety Authority of Member State “B” is required, but if the route(s) over which it is to operate in Member State B are not compliant with the relevant TSIs, then an assessment will have to be carried out.

This assessment is a specific Route Acceptance process. Its scope is to check the compatibility of the Rolling Stock with those routes....

**Scenario B** - The Rolling Stock has already been authorised to be placed in service in MS “A” according to Article 10(2)(b) of the Safety Directive (SD) and is not fully covered by the relevant TSIs. In other words either no TSIs exist that are relevant to the vehicle or MS “A” has notified additional national technical rules that the vehicle has been assessed to be compliant against. It is now required to be operated over a network in Member State “B”.

The vehicle would be authorised by the Safety Authority (SA) of MS B in accordance with Article 14 of the SD. It requires the RU (adding a NoBo report) to submit “evidence on technical and operational characteristics that shows that the rolling stock is in compliance with the energy supply system, the signalling and control command system, the track gauge and infrastructure gauges, the maximum allowed axle load and other constraints of the network”. In MS ”B” this can be satisfied by carrying out a route acceptance process under the responsibility of the SA of MS”B” for authorisation.

**Scenario C** - The Rolling Stock was been in service before the Safety Directive was adopted by MS “A” and is now required to operate in MS “B”.

It has never had any safety certification issued by MS “A”. There will be many cases of rolling stock that has been in use in Member States A or B before the current legislation requiring its approval by the safety authority. Such vehicles are said to have “Grandfather rights”. This scenario is not covered explicitly in either the safety directive or the interoperability directive.

However the RU applying for operation of the vehicle in MS ”B” will have a safety certificate Part (a) issued by Member State “A” in accordance with Article 10.2 of the Safety Directive. This may include application of TSIs and national safety rules, acceptance of staff certification of competency and authorisation to place in service the rolling stock used by the railway undertaking in accordance with Article 10.2 Part b). A NoBos report should be added.

Therefore the Safety Authority will have to consider, and when content accept evidence from the RU and NoBo that demonstrates that the vehicle(s) are safe to operate in Member State “A”. This evidence should be made available to the Safety Authority of Member State B in the form of a Technical File prepared by the RU. This Technical File will be part of the evidence required to enable operation of the vehicle in Member State B in accordance with Article 14.2. However, it will still be necessary to demonstrate that the vehicle will be compatible with the required routes for operation in MS ”B”. This must be done using the route acceptance process.
Once the respective RU & IM (and if needed a NoBo’s report) have reached agreement that the demonstration has been made, then it can be recorded in the Technical File that will have been created by the RU and the dossier submitted to the Safety Authority of MS “B” for authorisation.

**Scenario D** - The Rolling Stock was in service before the Safety Directive was adopted by the MS “A” and holds safety authorisation from the Safety Authority of that MS. It is now required to operate over a railway network in Member State “B”.

This is a variant of scenario C and all that is required is to carry out the route acceptance process. It is likely that a Technical File will already exist, although not necessarily containing all the information required by the Interoperability Directives. This will need to be expanded to contain demonstration that the vehicle is compatible with the routes required in MS ”B” and submitted to the Safety Authority of MS ”B” for authorisation.

**Scenario E** - The vehicle is brand new and has not yet been authorised in any Member State. Authorisation of the vehicle should be progressed in accordance with the Interoperability Directives in the Member State selected by the RU or manufacturer. Where the vehicle is required to be operated over a network that is not compliant to the relevant TSIs, then a route acceptance process would have to be carried out. The Safety Authority’ role is to endorse these route acceptance processes.

The Interoperability and Safety Directives provide the opportunity and the means to enable the cross acceptance of vehicles between Member States safely. The TSIs are yet not fully completed. However this requires a structured approach, as shown in the section below. The existing approach within the RIV has various limitations; it is not in full accord with the Interoperability and Safety Directives. Having said this, there have been examples of Member States cooperating on a bilateral basis to promote the cross acceptance of vehicles and operators. We present such an approach in the case study shown below.

### 6.2.2 Case study lessons

Acceptance process for ICE 3 and TGV/POS trainsets onto the French LGV E (High Speed Line East) and Germany’s routes towards Frankfurt and Munich.

DB, SNCF, DB Netz, RFF and their Safety Authority (EBA et DTT) together decided to build a common reference framework. The main sources used for drawing up the common reference framework for this joint German /French case study were the TSI and the existing national frameworks.

- When the TSI reference exists jointly with the German and/or French legal framework, the target was to take into account only the TSI reference.
- If necessary, some added elements or national complements have been included for safety of the traffic.
- It is important to note that some exemptions versus TSI were requested to the Authorities (DTT for the SNCF and EBA for the DB). These requests were done in the context of EC Directive 96/48 at the Article 7 (clause a).
- If no TSI reference existed, the mutual recognition of national frameworks was adopted as a guarantee for maintaining the same safety level.
- In case where mutual recognition is not possible, the application of national requirements was maintained.
The main advantages gained by this method are:

- Limitation of the admission costs by the superposition of national and TSI references,
- Optimisation and rationalisation of the lot of analysis and tests procedures necessary for the conformity demonstration for the two types of rolling stocks ICE3 et TGV,
- The mutual recognition of the EC conformity tests done by the Safety Authorities
- Take into consideration of the test already done,
- To present a European approach.

The EC should consider developing and designating routes which should be prioritised to be made compliant to the relevant TSIs. This will accelerate the simplification of the route acceptance process and hence reduce costs.

It is clear that the European legal framework affecting the acceptance of rail vehicles across the Member States is not yet finalised. However not all the TSIs and National Rules have been completed, or are yet in their final form, and many identify open points, or issues that are still the subject for discussion by Member States.

Furthermore it is likely to be many years before all railway routes meet the requirements specified by the TSIs.

However this need not restrict the cross-acceptance of vehicles requiring to work across different Member States. This section describes how the SAMNET deliverable believes that the current difficulties may be partially overcome through the following:

- Co-operation between IMs, RUs, and NoBos under the SA responsibility to ensure the safe operation of the railway system in compliance with the Safety Directive,
- Development and implementation of a cross acceptance process in each Member State that has been reviewed by the European Rail Agency (ERA) for compatibility with the Interoperability and Safety Directives and incorporating the route acceptance principles recommended in this section.
It is understood that this approach is proposed for the acceleration of the introduction of ERTMS level 2 detailed in Chapter 7 of the Control, Command and Signalling Conventional and High Speed TSIs.

In the medium term it may be possible for the EC to develop a harmonised cross acceptance process and guidance for inclusion within the safety certification processes in accordance with article 15 of the Safety Directive.

As routes become more compliant with the TSIs, the scope of the route acceptance process will reduce. Ultimately a rail vehicle, which has been authorised as being fully compliant with the relevant TSIs, will be able to pass over any route which has also been authorised, without any further assessment.

6.2.3 Comments and positions

Mutual recognition by the Member States of the EU of the verifications of conformity that they are responsible of performing or of having performed on the elements that are used in the rail system, is a cornerstone of the framework that must enable the free movements of trains, train personnel and train equipment in the European Union. Without this mutual recognition, trains, train personnel and train equipment are specific to each member-state and cannot cross borders.

Directive 96/48 EC on the interoperability of the European High-Speed Rail Network and Directive 2001/16 on the interoperability of the European Conventional Rail Network define for the complete European Union the regulations and technical documents enabling their implementation and the verification of conformity to the essential requirements, in particular those concerning safety.

Conformity to the essential requirements is the key to obtaining the trust of the stakeholders in respect to the level of safety resulting from the use of an element of the system regardless of its origin, owner or use.

When the directives are fully applied, mutual recognition will no longer be needed as the same rules and verification methods will be applied by all under supervision of the European Railway Agency.

The complete implementation of the directives imply their transposition by all Member-States, the publication of all Technical Specification for Interoperability (TSIs), the availability of all relevant European norms and …the conformity of the complete European rail network. This can be achieved only progressively and will not be completed before many years.

Indeed, currently as a first step TSIs for High Speed have been published and have entered into force. Once all TSIs for Conventional Rail have been published, national rules will be used only to ensure compatibility that elements conform to the TSIs and are hence interoperable with the network or the parts of the network not yet in conformity with the TSIs and where such elements will be in operation.

Position 82 The acceptance of rolling stock should be based on a common reference framework using TSI and national requirements.

Position 83 Each Member State should control the route acceptance process for rail vehicles, which encompasses the principles for interoperability and safety of operation defined in the Interoperability and Safety Directives.

Position 84 Route Acceptance should describe a process for the cross acceptance criteria for vehicles or routes that are not fully compliant with the TSIs. So the complete cross acceptance
process should be demonstrated by the IM, RUs and if necessary by NoBos, at the commencement of the process. The Safety Authority has to endorse this demonstration.

**Position 85** This mutual recognition must be based on the acceptance of the equivalence of the safety levels guaranteed by the regulations, the verification methods, the independence and competence of the bodies empowered by the States to perform these verifications and their follow-up.

**Position 86** Any element of the rail system certified in one Member-State must be recognised by another if in so doing it does not decrease the safety level and it is compatible with the parts of the network where it is in operation.

### 6.3 Assessment according to CENELEC standards and TSIs

#### 6.3.1 Reference system

This report gives the results of the examination of the use of CENELEC standards and TSIs in relation with national regulations and from an assessor’s point of view.

Safety requirements have always been taken into account in the development of the railway transport system. Nowadays, contractual obligations on performance have led manufacturers to a total control of parameters acting on Reliability, Availability, Maintainability and Safety (RAMS) in the field of railways. The choice of norms to be used is the designer’s and the manufacturer’s responsibility. But to have this done in openness and in a non-discriminatory manner, it is necessary that the State prescribes the safety requirements (e.g. safety targets) and the railway companies recommend the standards reference system.

The safety of railway projects are usually governed by laws and standards aimed at defining and achieving a certain level of RAMS requirements (EN50126, EN50129 and EN50128).

The assessor’s manual is based on the CENELEC reference system (EN 50126, EN 50128 and EN 50129) but it is also based on the results of several European projects concerning the certification and assessment of the railway system:

- CASCADE (Certification and Assessment of safety Critical Application Development) project ESPRIT 9032;
- ACRUDA (Assessment and Certification Rules for Digital Architectures);
- SQUALE (Security, Safety and Quality Evaluation for Dependable Systems);
6.3.2 **Analysis of the reference system**

The notified organisation’s Quality Manual describes its field of application and the activities carried out (conformity assessment and control and/or surveillance). The Quality manual presents the various accreditations:

- Accreditation for issuing “certifications through examination of types of products to be used in guided transports” in conformity with EN 45011 standard;
- Accreditation for carrying out “inspections” according to standard EN 45004.

It also describes the “notified bodies” structure according to directive 96/48/EC related to the interoperability of the high speed Trans-European railway system.

The major problem of the CENELEC reference system is related to the notion of “legal responsibility”. The CENELEC reference system does not make the link between the activities or the actors and it does not unambiguously assign responsibilities.

6.3.2.1 **TSIs**

The TSIs set the basic parameters and determine the constituents and the interfaces that ensure coherence of the Trans-European system. The TSIs specify a number of criteria that are to be fulfilled by the interoperable product. These criteria are as follows:

- General requirements for the subsystems and their interfaces such as safety, reliability, health, protection of the environment and technical compatibility (Appendix, Section 3 of the TSI [E3])
- Subsystem characterisation specifying functions, interfaces with other elements of the system, interfaces with other interoperable systems, performances (Appendix, Section 4 of the TSI [E3])

The TSIs are not standards for the appraisal of the conformity or of the fitness of use within the scope of the safety application.

6.3.2.2 **EN 50126**

Standard EN 50126 [Ref 15] is a guide, which only includes a few requirements. It represents all the phases required to design and to implement a system.

The application of this standard should be adapted to specific requirements of the system considered. To apply this standard to the system being considered, it is necessary to:

a) Specify and justify the phases,

b) Specify the obligatory activities and the requirements of each phase

In practice, we have never yet encountered such “additional specifications to this standard”. It is difficult for the assessors to understand and apply these standards. A great deal of effort will also be required to write the “application guide for the system under consideration”.

6.3.2.3 EN 50129

Standard EN 50129 [Ref 17]

- Specifies the content of a Safety Case;
- Specifies the requirements concerning the equipment according to the SIL level of the equipment;
- Requires the methods and tools to use at each stage of the life cycle of the system defined in NF EN 50126;
- Imposes an organisation of safety according to the SIL level.

6.3.2.4 EN 50128 [Ref 16]

CENELEC standard EN 50128 [Ref 16] has been developed by manufacturers and operators. It has been applicable since July 2001. This standard is applicable to system software aspects. It defines, for the safety levels of integrity (SIL) of the different software, the methods and techniques to be used to meet the specified safety level. Standard EN 50128 does not provide reference for programming rules associated to the development. Perhaps this standard can refer to other standards (e.g. MISRA suggests some rules for the C language).

6.3.3 Comments and positions

Position 87 The CENELEC reference system should specifically introduce a separation of roles and of responsibilities so as to contribute to the creation of unambiguous norms.

Position 88 The CENELEC standards (EN 50126 and EN 5128) do not clearly describe what the “mandatory requirements” are.

Position 89 The TSI proposed system hierarchy decomposition with some elements presented with different details and complexity on same levels.

Position 90 The certification reference system of interoperability of constituents is not clearly defined. For, the TSI Control/Command mentions in its appendix A, for each interoperability constituent, documents called “European specifications defining the fundamental parameters”.

Position 91 The CENELEC reference system (for EN 50126 as well as EN 50128) should propose a better formalisation of the SIL level. Standard 61508 for its part is better detailed.

Position 92 The CENELEC standard EN 50128 defines five Safety Integrity Levels (SIL). Level 0 corresponds to a non-safety-related equipment, whilst levels 1 to 4 are described as Safety-related. Do we really need 5 levels of SIL?

Position 93 The CENELEC standard EN 50129 required several analyses but specify only partially, how these have to be elaborated. For some analyses, e.g. Fault Tree Analyses or Failure modes, Effects, and Criticality Analyses, other standards exists such [34].

Position 94 The CENELEC standard EN 50129 defines five Safety Integrity Levels (SIL). Level 0 corresponds to a non-safety-related equipment, whilst levels 1 to 4 are described as Safety-related. In fact, we can still ask the following question: do we really need 5 levels of SIL?
Position 95 The CENELEC standard EN50129 does not describe (or only partially) how all the programmable integrated circuits are to be treated.

The CENELEC standards discussed in this deliverable provide good methods to avoid systematic or random faults in railway applications. The general and specific remarks made in this deliverable and related to the use of standards by a notified body are mainly focused on the interpretation of articles and the implementation of new technology and tools that are not mentioned in the standards.

Standards EN 50126, EN 50129 and EN 50128 are currently implemented in the railway sector. It is a shame that the CENELEC reference system is not yet subject to formalised training. It is a trade reference system that is “learned on the job” in companies. Apart from the previous remarks the standard EN50128 seems to be at very good level, very homogenous and clear.

Standard EN50126 is also at good level, but it is sometimes more confusing, notably through a lack of consistency in its vocabulary (for example all the “verification” paragraphs that confuse “verification” and “assessment” (§6.3.5, §6.4.5) activities. The assessor should be independent from the verifier; this leads to great confusion on the role of each entity.
7 Research strategy plan

7.1 The approach

The strategy plan for research needs was drawn up as part of the SAMNET project. It is concerned with the area of work on safety management and interoperability of European railways covered by the SAMRAIL project. It is also related to the Safety Directive. It is designed as an input to the decision making of the European Commission in respect to its research priorities for the coming five to ten years.

The report on research needs was developed by working group n°1 of SAMNET. A number of universities and research institutes took the lead in proposing the first draft (December 2004) [Ref 33], based on the recommendations of the SAMRAIL work packages. The draft proposals were presented at a number of meetings of the SAMNET Steering Committee, Technical Committee, as well as Workshops and User Group meetings during 2005 and were circulated to all SAMNET members [Ref 34]:

Based on the feedback from this consultation process and an analysis of the ERA work plan, the final report was prepared. The proposals coordinate the research planning that is already underway under the auspices of ERRAC, the UIC Safety platform and other international groups and that which is proposed under the EURNEX network. Further research planning needs to be coordinated with the national research programmes in railway safety.

The ERA will need to rapidly obtain a clear and comprehensive view on the various safety aspects affecting railways in Europe that will enable it to make judgments and recommendations on the risks arising from railway operation across Europe.

The proposed structure for organising the report on research needs was to take the safety management system loop, which was used to organise the work packages of SAMRAIL project, as a primary principle. This was modified during the course of the study to give the following set of headings, with the relationship shown in figure 11 below.

![Figure 11: System management of safety](image)

The first consideration was the life cycle of the railway system and its component parts as a subsidiary dimension for structuring the research needs. This identifies the steps of:

- Design, construction and particularly acceptance of hardware,
• Selection, training and competence testing of staff for the human elements of the system,
• Operation of the system, including operation under degraded circumstances and in emergencies,
• Maintenance and modification of the system and its elements.

• Secondly, the railway system may be considered as a transport system for passengers and freight door-to-door. This distinguishes the steps of loading and unloading freight and embarking and disembarking passengers and the activity of shunting as a possible focus of risk and of research to diminish it.

Another point of view considers the system as a concentric set of elements, identifying different groups of potentially affected persons and sets of interactions [figure 12]. This identifies some areas of concern for human factors research at the interface between hardware and those who operate and use it. It also locates aspects such as the effect of the railway system on its environment and other transport systems, which cross it (e.g. level crossings).

![Figure 12: System level interactions](image)

When considering the research proposals made, it is also necessary to take account of a number of other considerations about the railway system, which may be important in deciding where the focus of a given piece of research should be.

### 7.2 Research needs

The research items in the first list below were derived from the priorities given by the respondents to the circulation of the concept reports of the working group and to the presentations made at SAMNET meetings. The list reflects the view of those persons and organisations which provided feedback to the working group’s proposals. The list contains only the **11 top research topics** (total ranking from (1-32)), all other items have been given lower priorities:

• Railway risk control (Cost-benefit analysis),
• Cross acceptance,
• Human factors in risk assessment and safety cases,
• Common contents and formats of accident & incident statistics and investigations,
• Audit and review: performance indicators for the SMS,
• Elaboration of a comprehensive and consistent safety database (building on the existing UIC structure),
• Common model base,
• Common taxonomy,
• Risk tolerability criteria including legal considerations,
• Risk measurement unit,
• Operational Aspects of Interoperability.

The working group has included other items in the report, such as:
• Method for designing and assessing learning,
• Overall and specific structure of the SMS,
• Method to Assess the Safety of ERTMS Migration,
• Generic set of scenarios,
• Common tool support,

Although the following items received lower priority ratings, the working group has included them as being important prerequisites for high priority items, or as important for research in the medium term. Also all of the items received at least one high priority rating are included, so that the full deliberations of the group are reflected.

The spread of assessments given by the respondents also justifies this inclusion, since all of these items received at least one vote as high priority. The working group wishes to single out those items, which were not voted high priority by the respondents. The working group considers these to be topics of such importance in the medium term that research on them needs to be developed forthwith. A clear, integrated model base and method for risk assessment is a prerequisite for the development and choice of cost-effective prevention measures which optimise safety in a period of expanding traffic and changing technology. It also allows responsible choices between alternative safety philosophies, which have to be made in the process of achieving interoperability. Learning and improvement from pro-active performance assessments is also necessary to go beyond the trial and error learning from accidents and incidents. Both these items are characteristic of high reliability organisations and systems, such as the process industry and aviation.

These lists were developed in parallel with the other work of SAMNET and its working groups and should be read in conjunction with the conclusions of those working groups, as set out in this report. Some issues highlighted by WG1 have already received some attention in these working groups, which may alter the priority given to them. The working groups have also identified additional issues requiring research. A research plan needs to be a living document updated at intervals.

In many of the research areas described above, the issue was raised whether a generic approach, model or technique should be developed centrally or, whether high level criteria should be developed for assessing whether the existing approaches, models or techniques are adequate for their purpose. The response to the proposals reflected this, with those who have existing approaches, models or techniques reflecting the second viewpoint and those lacking these reflecting the first viewpoint. This is a higher level issue which the European Commission needs to resolve.
8 Conclusions

The process of creating an internal European rail market has just started. The introduction of the first railway package of European Directives has created a common framework for access to railway infrastructure, for licensing and safety certification and for allocation of railway infrastructure capacity. The second railway package was designed to expand this approach by adding the safety aspects, extending the work on interoperability to new areas and putting it all into a comprehensive, clear and consistent context.

During the period of the SAMNET project the European railway community has changed considerably in their roles and responsibilities and are still in the process of a privatisation and decentralisation programme in Europe. The originally monolithic organisation of the railways has been divided into a number of independent organisations, some of which have been redefined as commercial organisations and others as subsidiaries of the government.

The reorganisation process has been a confused one, with several changes in the way in which the division of responsibilities was envisaged, particularly those relating to rule making, inspection and enforcement. This reorganisation process has created a set of new obstacles in the communication and cooperation between all parties concerned. The reorganisation makes it difficult to give a clear picture of current good practice and of the division between problems which are structural, and those which are caused by the transition process.

According to the Safety Directive [Ref 1], infrastructure managers and railway undertaking have the responsibility for ensuring safe railway operation. These areas should be further developed and investigated in order to refine the existing national solutions and safety culture through good practice and to reach a common level of understanding.

The SAMNET project achieved a number of essential milestones towards establishing a the competitive but safe European rail system by developing key elements regarding the implementation of the safety directive. Wide consultation and dissemination (§3) were organised to develop and refine the main results of SAMNET.

The debate by the experts in the SAMNET consortium and the consultation with the different groups shows that the common safety targets, indicators and methods are closely linked and cannot be treated separately. It also shows that the basic element required to develop the common safety targets and methods is the establishment and the agreement of common definitions of railway system – a level playing field.

The use of the functional architecture of railway system developed by AEIF as a basis for risk apportionment is recommended. The approach (§ 5.1) proposed by the SAMNET project allows the definition of global safety targets according to the safety directive and the development of specific targets related to specific parts of the system based on AEIF architecture. The purpose of Common Safety Indicators (CSIs) is to monitor European railway safety performance.

It is essential that an agreed set of common safety indicators be used to ensure that measured safety performance of different organisations are realistically comparable and are related to the CSTs. The SAMNET project suggests (§5.2) the definition of global safety indicators in relation with the global safety targets prescribed by the safety directive. The specific indicators can be used for critical events and not be based on accidents (this is covered by Global Indicators). The common safety methods can
be based on existing tools and techniques used to develop a safe railway system. CSMs are required for ensuring that the various safety requirements put in place by an organisation are routinely and continually met by that organisation.

SAMNET further outlines that the CSM process (§ 5.3) should comprise the risk evaluation and assessment stages for the development and risk reduction and the control and monitoring stages for meeting safety requirements.

The CSM process should be based on existing known techniques (e.g. CENELEC 50126). The SMS guidelines developed by the SAMRAIL/SAMNET partners and disseminated was used for a case study to assess its applicability (Eurotunnel). The result of this case study suggests eleven elements to be addressed in any RU or IM SMS. These guidelines (§4) are in compliance with Railway safety directive requirements.

The key success of implementing an efficient SMS is the collaboration between IM and RU in order to maintain cohesive safety of the overall system. Although IMs are given an important role (see Safety Directive Article 9.3), there are no explicit provisions for them to check safety submissions of RUs who seek safety certificates to use the network. Similarly, RUs should have the opportunity to comment on the safety management system of the IM and of other RU that could affect their operation.

The economic aspect of the Safety Management System and Interoperability is a very important domain representing the business thinking relating also to the safety aspects in the reorganisation process of European Railways. Although the railway system is the safest system when compared with other modes of transport, it needs to be changed in a business-oriented way, making it more attractive to the transport market. Nevertheless, this restructuring of the railways should be managed in a cost-effective way to include technical developments and the management of safety.

The cross acceptance and certification process represents the third important aspect treated by SAMNET (§6). The main debate and discussions were focussed on Rolling Stock (RS) acceptance. One way to enhance the mutual recognition of RS is to develop a common reference framework based mainly on the RS TSI as well as national requirements. Such mutual recognition must be based on the acceptance of equivalent safety levels guaranteed by the regulations, the verification methods, the independence and competence of the bodies empowered by the Member States to perform these verifications and their follow-up. So, any element of the rail system certified in one Member-State must be recognised by the other if it does not decrease the safety level and it is compatible with the parts of the network where it is in operation.
9 Definitions and acronyms

9.1 Definitions

The definitions are from the safety directive (SD) [Ref 1] and CENELEC standards [Ref 15], [Ref 16] and [Ref 17].

[Def 1] **Accident** means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions, derailments, level-crossing accidents, accidents to persons caused by rolling stock in motion, fires and others (SD);

[Def 2] **Agency** means the European Railway Agency, the Community agency for railway safety and interoperability (SD);

[Def 3] **Apportionment**: A process whereby RAMS elements for a system are sub-divided between the various items, which comprise the system to provide individual targets (EN50126).

[Def 4] **Causes** means actions, omissions, events or conditions, or a combination thereof, which led to the accident or incident (SD);

[Def 5] **Common safety targets (CSTs)** means the safety levels that must at least be reached by different parts of the rail system (such as the conventional rail system, the high speed rail system, long railway tunnels or lines solely used for freight transport) and by the system as a whole, expressed in risk acceptance criteria (SD);

[Def 6] **Common safety methods (CSMs)** means the methods to be developed to describe how safety levels and achievement of safety targets and compliance with other safety requirements are assessed (SD);

[Def 7] **Common cause failure**: A failure which is the result of an event(s) which causes a coincidence of failure states of two or more components leading to a system failing to perform its required function (EN50126).

[Def 8] **Common mode fault**: Fault common to items, which are intended to be independent (ENV 50129).

[Def 9] **Cross-acceptance**: The status achieved by a product that has been accepted by one Authority to the relevant European Standards and is acceptable to other Authorities without the necessity for further assessment. (ENV50129)

[Def 10] **Dependent failure**: The failure of a set of events; the probability of which cannot be expressed as the simple product of the unconditional probabilities of the individual events. (EN50126)

[Def 11] **Diversity**: A means of achieving all or part of the specified requirements in more than one independent and dissimilar manner. (EN 50129)

[Def 12] **Element**: A part of a product that has been determined to be a basic unit or building block. An element may be simple or complex. (EN 50129)

[Def 13] **Equipment**: A functional physical item. (EN 50129)
[Def 14] **Error:** A deviation from the intended design, which could result in unintended system behavior or failure. (EN 50129)

[Def 15] **Failure:** A deviation from the specified performance of a system. A failure is the consequence of a fault or error in a system. (EN 50129)

[Def 16] **Failure cause:** The circumstances during design; manufacture or use, which have led to a failure. (EN50126)

[Def 17] **Failure mode:** The predicted or observed results of a failure cause on a stated item in relation to the operating conditions at the time of the failure. (EN50126)

[Def 18] **Failure rate:** The limit; if this exists; of the ratio of the conditional probability that the instant of time; T; of a failure of a product falls within a given time interval (t+(t) and the length of this interval; (t; when (t tends towards zero; given that the item is in an up state at the start of the time interval. (EN50126)

[Def 19] **Fault:** An abnormal condition that could lead to an error in a system. A fault can be random or systematic. (EN50126)

[Def 20] **Fault mode:** One of the possible states of a faulty product for a given required function. (EN50126)

[Def 21] **Fault tree analysis:** An analysis to determine which fault modes of the product; sub-products or external events; or combinations thereof; may result in a stated fault mode of the product; presented in the form of a fault tree. (EN50126)

[Def 22] **FMEA:** An acronym meaning Failure Modes and Effects Analysis. A qualitative method of reliability analysis which involves the study of the fault modes which can exist in every sub-product of the product and the determination of the effects of each fault mode on other sub-products of the product and on the required functions of the product. (EN50126)

[Def 23] **Function:** A mode of action or activity by which a product fulfils its purpose. (EN50126)

[Def 24] **Hazard log:** The document in which all safety management activities, hazards identified, decisions made and solutions adopted, are recorded or referenced. (EN50126)

[Def 25] **Hazardous event:** An occurrence that creates a hazard.

[Def 26] **Human error:** A human action (mistake), which can result in unintended system behavior/failure. (EN 50129).

[Def 27] **Incident** means any occurrence, other than accident or serious accident, associated with the operation of trains and affecting the safety of operation (SD).

[Def 28] **Infrastructure manager** means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof, as defined in Article 3 of Directive 91/440/EEC, which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings (SD);
**Interoperability constituents** means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem upon which the interoperability of the high-speed or conventional rail system depends directly or indirectly, as defined in Directive 96/48/EC and 2001/16/EC. The concept of a "constituent" covers both tangible objects and intangible objects such as software (SD).

**Investigation** means a process conducted for the purpose of accident and incident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes and, when appropriate, the making of safety recommendations (SD).

**Investigator-in-charge** means a person responsible for the organisation, conduct and control of an investigation (SD).

**Notified bodies** means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the EC procedure for verification of the subsystems, as defined in Directives 96/48/EC and 2001/16/EC (SD);

**National safety rules** means all rules containing railway safety requirements imposed at Member State level and applicable to more than one railway undertaking, irrespective of the body issuing them (SD);

**Product:** A collection of elements, interconnected to form a system, subsystem or item of equipment, in a manner, which meets the specified requirements. (EN50129).

**Occupational health and safety means** a safety culture and safety climate ensuring: safe and healthful employment and places of employment, i.e. workplaces which are free from recognized hazards likely to cause death or serious physical harm and working conditions in which injury and occupational illness, workplace hazards, worker protection and welfare are monitored and controlled so that work can be done safely as a result of appropriate prescriptive work planning and execution, focusing in particular on tools, training and equipment together with analysis and control of hazards [Ref 6]

**Railway authority:** The body with the overall accountability to a Regulator for operating a railway system. (EN50126).

**Railway system** means the totality of the subsystems for structural and operational areas, as defined in Directives 96/48/EC and 2001/16/EC, as well as the management and operation of the system as a whole (SD);

**Railway undertaking** means railway undertaking as defined in Directive 2001/14/EC, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only (SD);

**RAMS:** An acronym meaning a combination of Reliability; Availability; Maintainability and Safety. (EN50126)

**Random failure integrity:** The degree to which a system is free from hazardous random faults. (EN 50129)

**Random fault:** The occurrence of a fault based on probability theory and previous performance. (EN 50129)
Random hardware failures: Failures; occurring at random times; which result from a variety of degradation mechanisms in the hardware. (EN50126)

Redundancy: The provision of one or more additional elements, usually identical, to achieve or maintain availability under the failure of one or more of those elements. (EN 50129)

Risk: Likelihood of an event occurring and its consequences.

Risk analysis: Systematic use of available information to estimate the likelihood and consequences of hazards.

Risk assessment: Overall process of risk analysis and risk evaluation.

Risk reduction: A process of selection and implementation of options that is applied to reduce either the likelihood or consequences, or both, of a particular risk.

Safety: Freedom from unacceptable levels of risk. (EN 50129).

Safety authority means the national body entrusted with the tasks regarding railway safety in accordance with this Directive or any binational body entrusted by Member States with these tasks in order to ensure a unified safety regime for specialized cross-border infrastructures (SD);

Safety case: The documented demonstration that the product complies with the specified safety requirements. (EN50129)

Safety integrity: The likelihood of a safety-related system achieving its required safety features under all the stated conditions within a stated operational environment and within a stated period of time. (ENV50129)

Safety integrity level (System): A number, which indicates the required degree of confidence that a system will meet its specified safety features. (EN50129)

Safety life-cycle: The additional series of activities carried out in conjunction with the system life-cycle for safety-related systems. (EN 50129)

Safety management system means the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations (SD);

Safety process: The series of procedures that are followed to enable all safety requirements of a product to be identified and met. (EN 50129).

Safety requirements: The requirements of the safety functions that have to be performed by the safety related systems; comprising safety functional requirements and safety integrity requirements. (EN50126)

Safe state: A condition, which continues to preserve safety. (EN 50129)

Serious accident means any train collision or derailment of trains, resulting in the death of at least one person or serious injuries to five or more persons or extensive damage to rolling stock, the infrastructure or the environment, and any other similar accident with an obvious impact on railway safety regulation or the management of safety; "extensive damage" means damage that can immediately be assessed by the investigating body to cost at least EUR 2 million in total (SD);

Signalling system: Particular kind of system used on a railway to control and protect the operation of trains. (EN 50129)
Software Safety Integrity Level: A classification number, which determines the techniques and measures, that have to be applied in order to reduce residual software faults to an appropriate level. (EN 50128)

System life-cycle: The activities occurring during a period of time that starts when a system is conceived and ends when the system is no longer available for use. (EN50126)

Systematic failure: Failures due to errors in any safety lifecycle activity; within any phase; which cause it to fail under some particular combination of inputs or under some particular environmental condition. (EN50126, IEC)

Systematic failure integrity: The degree to which a system is free from unidentified hazardous errors and the causes thereof. (ENV50129)

Systematic fault: An inherent fault in the specification, design, construction, installation, operation or maintenance of a system, subsystem or equipment. (EN 50129)

Technical specification for interoperability (TSI) means the specifications by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the trans-European high-speed and conventional rail systems as defined in Directive 96/48/EC and Directive 2001/16/EC (SD).

Tolerable risk: The maximum level of risk of a product that is acceptable to the Railway Authority. (EN50126, IEC)

9.2 Acronyms

(1) ACRUDA Assessment and Certification Rules for Digital Architecture
(2) AEIF European Association for Railway Interoperability
(3) ALARP As low as is reasonably practicable
(4) ATP Automatic Train Protection
(5) CASCADE Certification and Assessment of safety Critical Application Development
(6) CEN European Committee for Standardisation
(7) CENELEC European Committee for Electrotechnical Standardisation
(8) CSM Common Safety Methods
(9) CST Common Safety Targets
(10) EBO Eisenbahn-bau und Betriebsordnung
(11) EDS Event Database Safety
(12) EN Euronorm
(13) EMC Electromagnetic Compatibility
(14) ERA European Railway Agency
(15) ETA Event Tree Analysis
<table>
<thead>
<tr>
<th>Term</th>
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<tbody>
<tr>
<td>ETCS</td>
<td>European Train Control System</td>
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<td>ETSI</td>
<td>European Telecommunications Standards Institute</td>
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<tr>
<td>FMEA</td>
<td>Failure Mode and Effect Analysis</td>
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<td>FOC</td>
<td>Freight Operating Companies</td>
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<td>FTA</td>
<td>Fault Tree Analysis</td>
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<td>FRS</td>
<td>Functional Requirement Specification</td>
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<tr>
<td>GAME</td>
<td>Globalement Au Moins Equivalent (Globally at least equivalent)</td>
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<tr>
<td>GSM</td>
<td>Global System for Mobile communications</td>
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<tr>
<td>GSM-R</td>
<td>Global System for Mobile communications -Railways</td>
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<tr>
<td>HAZOP</td>
<td>Hazard and Operability Studies</td>
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<td>HAZID</td>
<td>HAZard Identification</td>
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<td>HEART</td>
<td>Human Error Assessment and Reduction Technique</td>
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<td>Health and Safety Executive</td>
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<td>HUSARE</td>
<td>Human Safe Rail in Europe</td>
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<td>IM</td>
<td>Infrastructure Manager</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>MEM</td>
<td>Minimum Endogenous Mortality</td>
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<td>OHS</td>
<td>Occupational Health and Safety</td>
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<td>OHSAS</td>
<td>Occupational Health and Safety Assessment Series</td>
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<td>OSS</td>
<td>One Stop-Shop</td>
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<tr>
<td>PHA</td>
<td>Preliminary Hazard Analysis</td>
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<td>RAMS</td>
<td>Reliability, Availability, Maintainability, Safety.</td>
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<td>RCM</td>
<td>Reliability Centred Maintenance</td>
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<td>RU</td>
<td>Railway Undertaking</td>
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<td>SADT</td>
<td>Structured Analysis and Design Technique</td>
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<tr>
<td>SAMNET</td>
<td>SAfety Management and interoperability thematic NETwork</td>
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<td>SAMRAIL</td>
<td>SAfety Management in RAILways</td>
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<td>SCC</td>
<td>Safety Certificate for Contractors</td>
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<td>Safety Management System</td>
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<td>Train Operating Companies</td>
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<td>TSI</td>
<td>Technical Specification for Interoperability</td>
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10 References

10.1 European Directives and CENELEC standards


[Ref 7] Treaty of Amsterdam amending the Treaty of European Union, the treaties establishing the European Communities.


[Ref 9] Railway Safety Act, Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services, updated 2002.

[Ref 10] Canada Transportation Act, Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services, updated 2002.


[Ref 13] Canadian Transportation Accident Investigation and Safety Board Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services, updated 2002.

[Ref 14] Title 49 Transportation of the United States Constitution

10.2 SAMNET deliverables

[Ref 21] SAMNET Glossary, April 2003, SAMNET/INRETS/ELK/ WP0/SAMNET.
[Ref 23] D1.0.1 WP0 Project Brochure
[Ref 24] D1.0.2 WP0 SAMNET quality plan
[Ref 25] D1.0.3 WP0 SAMNET project plan
[Ref 26] D1.0.4: E.M.El Koursi “Six monthly Progress Report Period n°1: From 01.01.2003 to 30.06.2003” SAMNET/INRETS/ELK/ WP0/D1.0.4/V0
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[Ref 57] D2.3.1: “Framework for identifying sources, stakeholders and the nature of risks”, SAMRAIL/ALSTOM/WP2

[Ref 58] D2.3.2 – ‘Common methods risk analysis’

[Ref 59] D2.3.3 – ‘Risk reduction, control and monitoring’.

[Ref 60] D2.3.4 – ‘Information and data requirements for risk analysis’


[Ref 62] D2.4.1 – ‘Definition of risk’.

[Ref 63] D2.4.2 – ‘Approaches to derivation of risk levels and risk apportionment strategies’

[Ref 64] D2.5.1: Safety Approval and Cross-Acceptance” SAMRAIL/SNCF/JM/WP2.5/D.2.5.1/V02, September 2004.

[Ref 65] D2.6.0: “Organisational Learning from Accidents and Incidents in European Railways” TUDelft/D2.6.0, August 2004.


[Ref 70] D2.9: SAMRAIL synthesis report, December 2004

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[Ref 74] AEIF: ‘Report on the Representative Architecture’
[Ref 76] C.de la Garza, A.Weille-fassina “Sécurité de l’interopérabilité ferroviaire : guide méthodologique”
[Ref 78] Position paper of the UIC Safety Platform on the brochure by DB, ÖBB and SBB on safety management in European railway companies”27/01/2005
[Ref 80] Safety Management Manuel of The Railway Company, RWC”02/02/2005
[Ref 81] Gestion de la sécurité dans les entreprises ferroviaires européennes” 01/2005
[Ref 82] “Note de position de la Plate-Forme Sécurité sur la brochure élaborée par la DB, les ÖBB et SBB sur le management de la sécurité dans les compagnies ferroviaires européennes” 25/01/2005
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[Ref 94] Group harmonisation of Safety systems, “Reports of the national Investigation Body”
[Ref 96] Group harmonisation of Safety systems, “Rolling Stock Maintenance”
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[Ref 102] UIC leaflet 964
[Ref 103] UIC leaflet 965
[Ref 104] UIC leaflet 966
[Ref 105] UIC leaflet 967
[Ref 106] UIC leaflet 968
[Ref 107] UIC leaflet 969


