

ProM@in



Task I2:

European Harmonisation of Safety Approval -

Harmonisation of Safety Approval - practical steps through co-ordination of certification bodies

The need for harmonisation of safety approval has been addressed in the questionnaire as well as in discussions with responsible persons of different railways. Also, the nera study [1] has pointed out this need. The problem is closely connected with the implementation of a European RAMS database which can be used for quantitative analyses in the safety approval process.

State of the art

A unified safety approach for Europe has been addressed within the CENELEC standards EN 50126, EN 50128 and EN 50129. These standards, however, incur some problems:

Although the standard which is the basis of the work is agreed upon in Europe, certification with respect to this standard is still organised differently in each country. Some countries such as e.g. Italy have not yet set up a system or are in the process of doing so, e.g. the Netherlands. The organisations carrying out certification are the notified bodies. This raises the following problems.

- If a certificate is issued in one country, how can it be accepted in another country having a differently organised certification system?
- The quantitative analyses required for safety approval need additional guidance which is not supported by the standards.
- The CENELEC standards cover the main part of problems concerned with reliability, availability, maintainability and safety. However, additional national standards exist, e.g. for fire protection which must be followed in addition to the CENELEC standards.

From a practical point of view, manufacturers of railway equipment and railway companies have the following issues regarding certification in different countries:

The manufacturer has to bother about parallel certification in different European countries, since certification systems are different.

On the other hand, a national railway company procuring equipment from abroad has problems with foreign certificates. Formally, they are not in accordance with the national system, in addition it is not well understood to what extent they can be relied on.

The problem has been addressed in the nera study [1]. An approach mentioned there would be a European certification system. This, however, requires delegation of national responsibility to a European organisation. Then, notified bodies could be accredited according to this European system. A European notified body would have to be able to act within most parts of Europe, partially through local representatives and have knowledge of relevant and specific national regulations. Since political decisions would have to be taken for this approach, significant time would be required before such a system could become operational.

Currently, some certification bodies or notified bodies have established loose bilateral contacts, in some cases even contracts on collaboration have been concluded.

Problems to be addressed

Harmonisation of safety approval needs to address several problems. First, the benefits of establishing joint action of some national notified bodies have to be considered.

Then, the **current experience** in working together with other notified bodies must be gathered. Trying to generalise this experience helps in defining the means for further and more intense collaboration. The approach adopted by ProMain is complementary to the approach proposed by nera. ProMain focuses on the certification bodies and their collaboration at a more technical level.

The information on the collaboration is intended to be made publicly available through the ProMain website so that a manufacturer wishing to certify his products in several countries can get information on how to do this and with the help of which organisation. On the other hand, this information is also important for the railway companies when foreign certificates must be assessed. This will then form a **support centre** for certification issues.

Also a comparison and equivalence study of national safety requirements and standards in other areas besides railways will assist in harmonisation.

In addition, guidelines on quantitative risk analysis will be given to assist in defining the safety integrity level and to prove the achieved **level of safety**. This is one of the most important problems and support is helpful for manufacturers as well as for assessors. Moreover, the information helps in applying a unified approach.

Also this information will be made available on the ProMain website.

Expected benefit

The expected benefit would be threefold:

- The collaboration of notified bodies will anticipate official regulations from the European Commission. National notified bodies will be better prepared for a European accreditation.
- Manufacturers will be able to easily certify their equipment in several European countries in parallel without having to repeat the process for each country. This will lead to substantial cost savings.
- National railways will have a better basis to trust foreign certificates and will be able to accept them also from a formal point of view if they are issued by a partner of a national notified body and possible small differences are covered by this national organisation.

General approach offered by ProMain

Phase I

In the first phase a study has to be elaborated covering the following issues:

- Current national status of existing notified bodies or organisations planning to become notified bodies.
- Gather experience of collaboration, especially on existing bilateral contacts and contracts.
- Study the means of co-ordination of notified bodies.
- Establishing a comparative list of additional national standards that have to be considered in addition to CENELEC standards, intended to be freely used from the web.
- Compiling guidelines for quantitative analysis in form of a cookbook containing examples.

Moreover,

- Contacts will be established with further railway representatives and certification bodies. A major role is to be played by UIC and UNIFE as international organisations.
- The results will be distributed via the the ProMain website, partially for free use, partially for members and experts of the website. The main intention is to develop a list of notified bodies in Europe, their contacts with other notified bodies and the current status of co-ordination of certification in different countries.

Phase II

A workshop will be conducted for notified bodies and representatives of railways and manufacturers. This workshop is intended to become the start of an international advisory group of notified bodies, driving further collaboration in a European perspective.

Possible multilateral contacts / contracts are encouraged. Therefore, a consultation group of notified bodies is to be founded.

Other work to be done in phase II is mainly based on the outcome of the study performed in phase I.

References

- [1] nera, Safety Regulations and Standards for European Railways, November 1999 study
- [2] EN 50126, EN 50128, EN 50129

Further information on this task

can be obtained from:

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