

**SUMMARY OF RESPONSES TO DEPARTMENT OF TRANSPORT
CONSULTATION ON INTEROPERABILITY**

EXTRACT ON SAFETY VERIFICATION (Q8)

(INCLUDES HSE COMMENT IN RESPONSE)

8) What are your views on the application of Safety Verification (Part 5 of draft ROGS Regulations) on the mainline railway?

8.1 In support of the proposals, some respondents acknowledged that there was a need for safety verification on the domestic railway and appreciated the arguments for applying this process to the non-interoperable mainline railway. Of those who were comfortable with the approach, comments indicated that safety verification was the most sensible solution for railway systems functionally separated from the mainline, and was an improvement on the Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994 (ROTS) that appeared to deliver a fairer and more impartial system of verification. It was also mentioned that the split between authorisation using the Notified Body (NoBo) process and second and third party verification dealt adequately with safety risks without imposing undue costs and burdens on the rail industry.

8.2 However, the majority of industry responses from various sectors, many of which were largely duplicated, were critical of the proposed system of safety verification as drafted in the Consultation Document. Concerns ranged from points of principle to those in practical terms and a summary is provided below.

8.3 Most respondents who were not in favour of safety verification suggested that the proposed policy added little value to an industry that already devoted a great deal of resources towards ensuring safety. Some respondents held the view that the argument for safety verification was circular. This was because on the one hand, if it was stated that the disapplication of ROTs created a safety gap which would be filled by safety verification, and if on the other it was claimed that the industry should feel comfortable as safety verification was largely done already, it followed that there was never a need for ROTs and there would be no safety gap that required filling.

8.4 Others took the view that the checking of designs and testing would not necessarily diminish with the demise of ROTs and the Railway Safety Case Regulations as the Safety Authority would still be responsible for approving the Safety Management Systems (SMS) of Infrastructure Managers (IM) and Railway Undertakings (RUs). The Safety Authority would also enforce its

practical application. It was maintained that this should provide the Safety Authority with significant assurance that both the Interoperable and Domestic network would continue to be suitably approved and controlled.

8.5 Many respondents also questioned the merits of imposing two separate approvals processes for different aspects of one project, i.e. that it could be subject to authorisation under interoperability and safety verification. Running two approvals processes in parallel could result in the potential for duplication between a NoBo and the independent Competent Person since there would continue to be interfaces between infrastructure subsystems.

8.6 The use of As Low As Reasonably Practicable (ALARP) principles in safety verification, but absolute standards in TSIs in third party NoBo assessment would, according to NoBos and some others, be an unsatisfactory and confusing situation, potentially resulting in a serious safety oversight. It could also prove to be burdensome financially, reduce consistency of assessment and cause unexpected time delays. Responses from NoBos suggested that a single organisation undertaking both approvals processes would avoid duplication and stop issues from falling between the two systems. Most respondents however, wished to simply emphasise that both processes should not run in parallel.

8.7 Some respondents suggested that the Approved Safety Requirements (ASRs), which support safety verification, were not comprehensive and fell short of the standard set by Railway Safety Principles and Guidance (RSPG), particularly for a new set of rules. It was claimed that the ASRs were characterised by open-ended words like 'sufficient' and 'should', even when there was a legal duty to comply. On the other hand, many of the ASRs required risks to be minimised without mention of '*as far as is reasonably practicable*' thereby making the requirement difficult to comply with under normal contractual arrangements between the designer/manufacturer/builder and contracting entity.

8.8 The majority of respondents, including those in support, felt that the safety verification proposals lacked detail and required more clarity in terms of its application and implementation. The extent to which safety verification would be applied and the form it took could vary considerably depending on interpretation and introduced uncertainty.

8.9 Most respondents highlighted the following as areas where detail was lacking:

- Definitions of, and criteria for 'significant safety risk', 'independent', and 'competent person';
- a defined assessment process; and
- a clearly defined scope of work for the independent competent person.

8.10 Some asked for consideration to be given to availability of suitably competent people in specialised industry sectors like heritage and light rail. Some were concerned that the independence requirements appeared less

prescriptive than that required for interoperability. Of those respondents, some thought that the independence requirements should correspond to the risk so that the highest potential risk issues required the most rigorous verification.

8.11 The heritage sector suggested that the draft ROGS Regulations interfered with ORR's duties under primary legislation to secure safe construction and operation of railways, and protect the public, by not requiring operators to seek approval directly from them. Furthermore, third party verification, in the absence of second party expertise, would place an unfair and disproportionate cost on a sector of the rail industry that did not receive public subsidies by being charged a fee. It was claimed that this also went against assurances given to the Lords for the protection of heritage railways against such charges.

8.12 It was feared by many that safety verification would result in increased costs at a number of levels. Responses suggested that even if a competent person could be identified to verify safety, particularly in the light rail and heritage sectors, professional indemnity and public liability insurance would be difficult to obtain. The Regulations would most likely result in increased premiums and fees for external consultants.

Revised proposals discussed with key stakeholders

8.13 In light of the concerns outlined above, HSE began to consider possible amendments to the proposals during the consultation period, and involved some industry groups in this process. Responses from stakeholders who had been involved in these discussions tended to be more supportive. They appeared to agree that the best way to enforce an appropriate level of safety verification in the future was through an IM's or RU's SMS. Some respondents appeared to support this in principle but wished to reserve comment until further details were available.

8.14 Of those who did comment on the revised proposals, most felt the revisions delivered 'simplicity and certainty' as major projects would be covered by interoperability and projects below the threshold would be controlled by a SMS. The Guidance needed to reflect the consensus developed with industry on the level of the threshold. This would reduce 'regulatory surprises' especially for larger projects where the certainty of the formal process was essential.

8.15 However, there was concern that there would be a risk of reactive intervention by the Safety Authority if it judged that there were shortcomings in industry's approach. To address this, it was suggested that for those projects not covered by interoperability, the Regulations should not allow the Safety Authority to overturn a verification completed as part of the SMS, although it would be reasonable to check that the due process described in the SMS had been carried out.

Comment:

8.16 In light of the feedback received during the consultation process, HSE has continued to work with industry to address some of the issues raised and has revised its proposals for safety verification. These new proposals for safety verification have not yet been endorsed by the HSC but they are expected to be presented to the Commission for approval in February 2006.

8.17 To clarify the current position, the safety verification process will need to be completed prior to new or altered infrastructure or vehicles being 'placed into service'. However, safety verification will not apply where the Interoperability Regulations apply, as an authorisation under the Interoperability Regulations will be treated as satisfying the requirements of safety verification. New proposals require a Dutyholder to evaluate a scheme against a "difference" and then a "risk" test. If the scheme is significantly different from that which is currently found on the transport system, and it would create a new risk or significant increase to an existing risk, then there would be a requirement on the Dutyholder to draw up a suitable written verification scheme for the proposal.

8.18 The Dutyholder would appoint the Competent Person(s) and then set out the verification scheme, including the verification criteria taking into account the advice of the Competent Person(s). The Dutyholder would retain the written record of this verification scheme and document this process as part of the SMS to demonstrate how the management system continues to deliver statutory requirements (ROGS Schedule 1).

8.19 The revised proposals reflect the suggestions made by many respondents to incorporate safety verification into the SMS. By doing so, it addresses the issues raised of the potential for two approvals processes running in parallel, and confusion regarding issues of duplication and consistency of assessment. With safety verification as part of a Dutyholder's SMS, the supporting ASRs would no longer be required, although these were largely designed for, and developed with, the non-mainline sector originally. Removing the ASRs, removes the concerns raised about them in the consultation.

8.20 HSE is currently considering the areas where respondents felt further detail was required and will revise the Guidance accordingly to ensure it provides clarity and further detail on definitions and criteria as necessary. Industry has also offered direct input into the Guidance on the sections covering co-operation and the process of safety certification and authorisation, which includes the SMS. The Guidance will be launched to support the Regulations when they come into force.

8.21 HSE has met with representatives from the various sectors affected by the revised proposals to explain the proposed amendments and seek early feedback.

8.22 The changes that HSE has made to the Regulations will result in a simplification of the safety verification process and will make compliance easier without compromising safety. The revised approach maintains the same policy objectives and outcomes of the original consultation document.

8.23 Some issues that industry raised about increased costs, particularly relating to third party verification, may also be addressed by the changes that have been made to the safety verification process.