Can prescriptive and performance-based risk management coexist?

Duijm, Nijs Jan

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Nijs Jan Duijm, DTU Management Engineering, nidu@dtu.dk

Abstract
This presentation deals with the possible conflict between the application of prescriptive standards and regulations and performance-based risk acceptance criteria.

Prescriptive standards and regulation provide instructions how to solve specific engineering problems; based on experience or by applying safety factors, the solution that is based on those standards are implicitly accepted to be “sufficiently safe”, or in order words, the residual risk is considered to be negligible.

Performance-based standards and regulations set an explicit risk criterion and leave it to the engineer/designer to demonstrate that the chosen solution meets the criterion.

Performance-based approaches have been promoted over the last decades because they promote and enable innovative solutions. It is the back bone of the European Commission’s legislative framework for creating the EU’s single market, known as the “New Approach”, and recognizable through the well-known CE mark.

However, prescriptive standards are much easier to apply, especially when conventional solutions are appropriate. Many of the European harmonized standards, even under the “New Approach” umbrella, are therefore prescriptive. And this is no problem, as long as there are no conflicts between the two approaches.

However, conflicts may arise, and in this presentation I will give two examples.

The first example deals with the use of a harmonized standard in a situation where the regulator uses an explicit risk acceptance criterion. The second example deals with a situation where European Commission regulation within the same legislation applies prescriptive and performance based criteria.

The first example deals with cooling installations based on ammonia, as used in slaughter houses and diaries. Many of these facilities are close to residential areas for historical reasons, and formerly used CFC as the refrigerant. The Danish authorities, in an attempt to control major hazards in residential areas, extended the “Seveso” rules to cover ammonia facilities containing more than 5 ton of ammonia when less than 200 m apart from residences. The authorities responsible for safety of the residence require demonstration that certain levels of individual (locaional) risk are not exceeded. Operators however, refer to the EN 378 series of harmonized standards, and that their installations have been approved by the national occupational safety authorities in accordance to this standard. Three conclusions could be drawn from this exercise:

1. The EN-378 standards do not include an explicit risk criterion, and therefore it cannot be used to a show compliance with a quantified risk criterion;
2. Traditional technical process risk analysis showed that an installation built and operated in accordance to the standards may violate the risk criteria for residential areas, and
3. Standards that are directed to controlling occupational safety (such as EN 378) may not deal with risk to third parties (residents) in an appropriate way, because the residual risk is not negligible for the exposed part of the population as compared to normally applied risk criteria.

The second example deals with the European Commission’s regulation on railway safety and common safety methods for risk assessment (CSM-RA). In this regulation the Commission recommends three principles for risk acceptance: “Use of codes of practice”; “use of a reference system”; and “explicit risk estimation and evaluation”. In this presentation we will focus on the first and last principle. In general, whenever possible, the operator will try to refer to a code of practice to demonstrate that some hazard is properly controlled. Those codes do not (normally) include an explicit safety level: if built and constructed according to the codes, the residual risk is considered negligible. Only if it is not possible to use an existing code or standard (e.g. because an innovative solution is chosen), use will be made of the principle “explicit risk estimation and evaluation”. To apply this principle some explicit risk criterion is required (and the regulator provides some criteria for some type of systems). Now the problem appears especially in cases where the majority of elements in a system can be designed and constructed according to codes of practice, but there are some issues or deviations in the design, that are not covered or fail to comply with those codes. An explicit analysis is than required, and e.g. additional safeguards implemented. However, if the safety-level of the code of practice in itself is not known, what requirements have to be put to the additional safeguards to ensure that the chosen solution is equally safe, or slightly safer, than the “full” implementation of the code?