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Process of Judging Significant Modifications for Different Transportation Systems compared to the Approach for Nuclear Installations

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ABSTRACT: The implementation of the CSM regulation by the European Commission in 2009 which harmonizes the risk assessment process and introduces a rather new concept of judging changes within the European railway industry. This circumstance has risen the question how other technology sectors handle the aspect of modifications and alterations. The paper discusses the approaches for judging the significance of modifications within the three transport sectors of European railways, aviation and maritime transportation and the procedure which is used in the area of nuclear safety. We will outline the similarities and differences between these four methods and discuss the underlying reasons. Finally, we will take into account the role of the European legislator and the fundamental idea of a harmonization of the different approaches.

1 INTRODUCTION

Modification is inevitable within any type of business and arises from the need to respond and adapt to varying conditions. Modifications may be required to the equipment, operational policies, and organizational structure or personnel. Whenever a modification is made, the potential consequences of that modification should be assessed before implementation.

In the area of European Railways the release of European Commission regulation 352/2009 (2009a) has led to a new approach regarding the Safety Management which is called Common Safety Methods (CSM). One part of this CSM is a new process for judging the significance of a proposed modification. After the analyzation of this process for judging modifications we will discuss the approaches used in the transport sectors of aviation and maritime transportation.

A next step all three approaches used in the transport sector are compared regarding their structure, the role of the proposer, expert organization and regulatory body within each method and the relevant aspects which are used for the determination of the significance.

Furthermore, we will take into account experiences in another area of high public interest regarding safe operation, the procedure to classify modifications in nuclear power plants (NPPs) is included as it is used in the German Federal State of Baden-Württemberg.

2 MANAGEMENT PROCESS FOR THE COMMON SAFETY METHOD APPLIED TO RAILWAY SYSTEMS

The revised CSM regulation 402/2013 (EC 2013) contains the description of the CSM approach. Main

part is the harmonized risk assessment process which has to be applied for all safety relevant and significant changes and which is shown in Figure 1.

Against this background, the significance of the change and its determination become a fundamental element of this risk assessment process. For the determination of the change the proposer shall apply the following six criteria which are described in Article 4 of the CSM regulation:

1 failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system under assessment;
2 novelty used in implementing the change: this concerns both what is innovative in the railway sector, and what is new for the organization implementing the change;
3 complexity of the change;
4 monitoring: the inability to monitor the implemented change throughout the system life-cycle and intervene appropriately;
5 reversibility: the inability to revert to the system before the change;
6 additionality: assessment of the significance of the change taking into account all recent safety-related changes to the system under assessment and which were not judged to be significant.

In this respect there is no further guidance for the application of these criteria. Due to this uncertainty with the correct application different approaches were developed on the basis of the given criteria and the relevant parts of the CSM regulation which are broadly discussed in (Petrek 2014a). Besides the correct understanding of the criteria and what they assess, also the weighting of the criteria and the threshold value above which a change is significant is not given by the regulation itself. The determination of this two elements by the application of multivariate statistics is described in (Petrek 2014b).

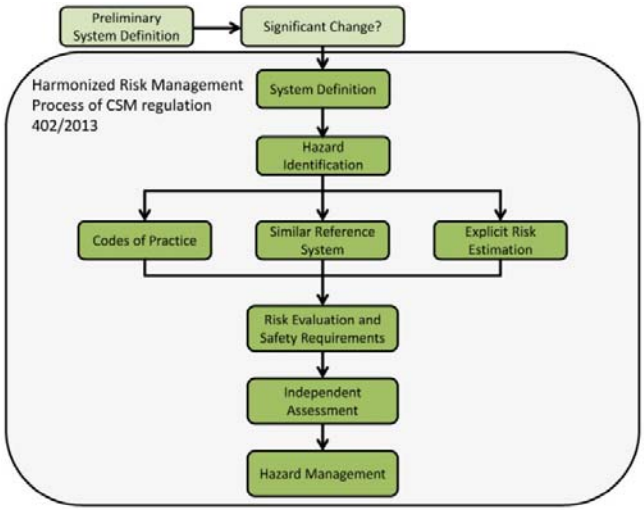

Figure 1. Harmonized Risk Management Process of CSM regulation No. 402/2013.

(Petrek 2014a) also develops the framework for judging the significance of a change which is shown in Figure 2. In this figure the assessment of the safety relevance and significance of the change are part of the light blue box. First step of the whole process is the analysis, if the change falls within the scope of the CSM regulation followed by the consideration of the criterion "Additionality". This consideration takes into account, if there were any safety relevant changes within the same area of the proposed change which were non-significant.

If the change is considered as significant by the application of the criteria, the proposer has to evaluate the associated risk itself and how it will be managed.

The purpose of the process of Figure 2 is to classify the proposed change into categories. A change, which is neither safety related nor does fall within the scope of the CSM regulation, results in the end of the CSM process. Thus, there is no further assessment of the significance of the change and no application of the harmonized risk management process but, in turn, an application of QM-Procedures, if such procedures are required by the Safety Management System (SMS) of the company. For example, the substitution of faulty components of the door control of a train with structurally identical components does not require the further application of the CSM risk management process.

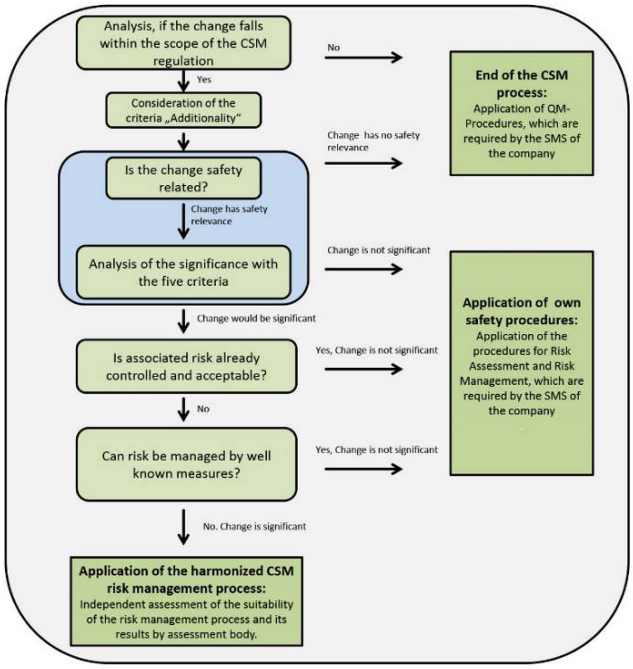

Figure 2. Caption of the framework of the CSM risk management process.

Furthermore, the application of own safety procedures is required for those changes which are safety related but not significant or which are significant due to the analysis of the criteria but the proposer decides that the associated risk is either already controlled or can be controlled by well-known measures. Only for significant changes which include risks that cannot be controlled by well-known measures the proposer has to apply the harmonized risk management process.

The application of an own safety procedure and the application of the harmonized risk management process are distinguished regarding the participation of an independent assessment body. Within the

harmonized process an independent assessment body must check the suitability of the chosen methods as well as the results of the risk management process.

Consequently, the significance of a change is not decisive whether a risk management process has to be applied or not but determines if an independent assessment is required or not. In this context, the four qualitative criteria innovation, complexity, monitoring and reversibility consider if there is any experience with the change itself and its implementation or not. Therefore, it is more likely that a change is significant, if there is only little experience with the proposed change within the company where the change takes place. Against this background, the implementation of new technology like the first-time use of LED technology within the signaling system for railways represents an example for a significant change. On the other hand, adding a new function to an electronic interlocking is a complex task and the interlocking is also highly safety relevant. However, the company which implements this type of change usually has the experience to do so and uses well-known practices. Therefore, in this case the change is not significant and the company has to apply its own safety procedure without the participation of an independent assessment body.

3 APPROACH TO EVALUATE CHANGES IN AVIATION

In the area of European aviation the European Aviation Safety Agency (EASA) is responsible for the safety management and the certification of aviation products within the European Union (EU). One main element of the safety management within the EU is the Commission Regulation No 748/2012 (2012), which lays down implementing rules for the airworthiness as well as for the certification of aircraft and related products and the certification of design and production organizations.

Article 2 of this regulation constitutes that products, parts and appliances shall be issued certificates, which are specified in Annex 1 (Part 21) of the Commission Regulation. Also design and production organizations which are responsible for the design respectively the manufacture of products, parts and appliances have to demonstrate their capability. Moreover, Section B of this Annex addresses the type certification and the relevant procedures for issuing these type-certificates. Basis of the type certification are the applicable airworthiness code and any relevant special condition. These special conditions refer to aspects of the product which may be unusual regarding the design features or practices as well as to unconventional use of the product or unsafe conditions which may appear during operation. Additionally, the type-certificate has to contain the demonstration of compliance with the environmental requirements which refer to noise and emission requirements and it has to be shown that “no feature or characteristic makes it unsafe”. Furthermore, any aircraft type-certificate requires a type-certificate for the engine or the propeller installed in the given aircraft.

The given Commission Regulation distinguishes between repairs and changes. Speaking of changes, point 21.A.19 of Subpart B describes a “change in design, power, thrust or mass [which] is so extensive that a substantially complete investigation of compliance with the applicable type-certification is required”. In this case, the changed product can generally be regarded as a new product which requires a reinvestigation of compliance with the airworthiness requirements. An example for a substantial change in this area is the change in the number or the location of engines of an aircraft.

Beside these substantial changes, Subpart D addresses further changes to type design and type-certificates and describes the procedures which have to be done by the proposer. For this purpose, proposed changes to a type design are subdivided into three categories: standard changes, minor and major changes whereas substantial changes described above are also major changes. According to point 21.A.90B, standard changes refer to aircrafts of 5.700 kg Maximum Take-Off Mass (MTOM) or less as well as to rotorcrafts, sailplanes, balloons or European Light Aircrafts. For standard changes acceptable methods, techniques and practices issued by the EASA for the identification and implementation of standard changes have to be applied. If these conditions are met, a change is regarded as a standard change and is not subject to an approval process.

Changes in type design which are no standard changes are classified into minor and major changes. In this respect, point 21.A.91 of Subpart D describes that a change is regarded as a minor change, if it has no “appreciable effect on the mass, balance, structural strength, reliability operational characteristics, noise, fuel venting, exhaust emission, or other characteristics affecting the airworthiness of the product”. All other changes are regarded as major changes. This classification determines the further proceeding for the implementation of the change. Minor and major changes to a type design have to applied in form and manner determined by the EASA. According to point 21.A.93 the application has to include a description of the change which identifies all parts of the type design and the approved manuals affected by the change. In addition, the application has to outline “the certification specifications and environmental protection requirements with which the change has been designed to comply”.

Minor changes have to be approved either by the EASA or by an appropriately approved design organization. Furthermore, minor changes require a record-keeping for each change. Moreover, variations in instructions for continued airworthiness due to the change shall be made available to all known owners of affected products. Nevertheless, this type of approval is only possible, if the applicant shows that the change meets the applicable certification specifications of point 21.A.101 regarding the compliance with the airworthiness code and the environmental protection requirements. In this context, the single installation of a GPS-based Flight

Management System without any new functionality or technology and which is, in addition, not linked to the autopilot is regarded as a minor change.

The applicant for a major change in turn has to fulfill the requirements of point 21.A.97. At first, he has to submit relevant data for the inclusion in the type design together with the demonstration of the compliance of the changed product with applicable certification specifications and environmental protection requirements. Moreover, the applicant has to demonstrate compliance with the type-certification basis. In order to demonstrate this compliance with the type-certification basis, the applicant has to perform inspections and tests according to point 21.A.31 and, if necessary, also flight tests according to point 21.A.33. In order to get the issue of approval described in point 21.A.103, the applicant also has to demonstrate that in case of not complied airworthiness provisions an equivalent level of safety is provided by compensating factors. Additionally, it has to be shown that "no feature or characteristic makes the product unsafe for the uses for which certification is requested". In contrast to the example of a minor change, the single installation of a GPS-based Flight Management System which has a dedicated linkage to the autopilot or the dual installation of such a system is regarded as a major change.

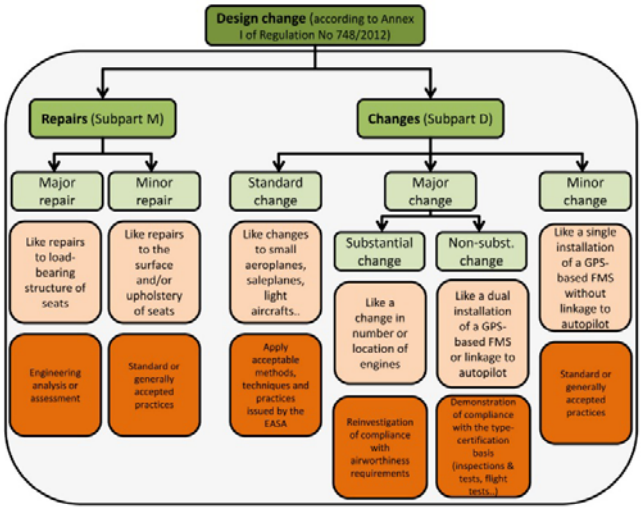

Figure 3. Classification of design changes according to Commission Regulation No 748/2012.

Repairs in turn are regulated by Subpart M and a repair is defined as follows: "A repair means elimination of damage and/ or restoration to an airworthy condition following initial release into service by the manufacturer of any product, part or appliance." Furthermore, an "elimination of damage by replacement of parts or appliances without the necessity for design activity shall be considered as a maintenance task" which requires no further approval. Comparable to the classification of changes, standard repairs are not subject to an approval process. The conditions for standard repairs are oriented to the conditions for standard changes which are described above. On the basis of point 21.A.435, all but standard repairs are classified as major or minor repairs and this classification shall be made in accordance with the criteria which are defined within point 21.A.91 for the classification of changes. Against this background, repairs to the load-bearing structure of an aircraft seat are regarded as a major repair which requires some kind of engineering analysis or assessment (IAA 2010). Whereas minor repairs like a repair which is limited to the aircraft seat and its surface and upholstery only require standard or generally accepted practices. Figure 3 shows the overview of the exposed procedure for the classification of changes within the European aviation sector.

The assessment of changes in the area of European aviation, the evaluation of modifications in European air traffic management with the Safety Scanning Method is discussed in (Petrek & Berg 2015).

4 ASSESSMENT OF MODIFICATIONS AND CONVERSIONS OF SHIPS

If a modification of a ship is technically inappropriate, poorly executed, its risks poorly understood, or management fails to ensure communication to key personnel, accidents or other undesired consequences can result. Thus, a formal and effective management of modification program plays a critical role in preventing accidents and losses (ABS 2013). It requires organizational support, assignment of necessary resources, and a clear, defined process. Therefore, guidance to the maritime and offshore industries is offered (e. g. ABS 2013) as a tool to aid in the development and implementation of an effective management of modification strategy to optimize existing risk management efforts.

Modifications and conversions of qualifying ships are zero-rated under Group 8, items 1 and 2 of VTRANS 120200 provided, after modification or conversion, the ship remains a qualifying ship (VTRANS 2010). This includes, for example:

- rebuilding or lengthening of a ship,
- updating or improvement of serviceable equipment,
- structural alterations.

It is important to note that this provision requires the ship to be qualifying before the modification work is started. This means that the modification or conversion of a non-qualifying ship is not zero-rated even if the modification or conversion results in a qualifying one. However, after conversion the ship will then be treated in the same way as any other qualifying ship for future supplies.

For example, the conversion of a trawler (gross tonnage of 20.72 tons) to a vessel designed for commercial scientific research would be zero-rated under Group 8, item 1. The services of modifying a 14 ton ship to be a 16 ton ship would not be zero-rated as the modification is not of a qualifying ship. Where a contract to supply modification services across a fleet of ships is being undertaken it is permissible for parts being modified to be removed from one ship, be modified, and then installed in a sister-ship whose parts are similarly destined for another sister-ship after modification.

The interaction between ship repair and ship conversion is also discussed in (Senturk 2011).

There are various different kinds of conversions but no commonly defined definition does exist. Repairs in accordance with approved drawings and documents are not considered to be a conversion. A conversion includes, e.g., any modifications on board of a classed ship which deviates from the approved drawings or an increase of the maximum allowable draft. Considering the various scope of conversion issues it is to be noted that some modifications may be regarded to be so-called major conversions which is comparable to significant modifications in other transportations systems and in the nuclear field.

The definition of a major conversion is to be distinguished from above definition of a conversion. The definition of a major conversion is individually provided in the applicable statutory instruments (SOLAS, Marpol etc.). However, a major conversion does include but is not limited to each modification which substantially alters the dimensions or carrying capacity or engine power of the ship as all these measures do normally imply new requirements which are to be observed. Major conversions normally do imply complete application of rules effective at the time of conversion. Moreover, any conversion which substantially alters the energy efficiency of the ship and includes any modifications that could cause the ship to exceed the applicable required energy efficiency design index as set out in regulation 21 is a major conversion (MEPC 2011).

A major modification of a ship is, for example, the change of the type of vessel, e.g., from a cargo ship to a passenger ship in order to carry more than 12 passengers. In this case, the applicable rules for the whole ship are to be applied as in the case of a new built. A simple replacement of the engine the regulation is not to be applied to the whole ship. The new components must comply with the latest regulations. Another example would be an extension of a passenger vessel by a new inserted section. This might be seen as a significant modification; however, it has been agreed that the current rules as for a new built ship is applicable only for the new section.

As already indicated in the maritime transportation the ships are classified. The objective of ship classification is to verify the structural strength and integrity of essential parts of the ship's hull and its appendages, and the reliability and function of the propulsion and steering systems, power generation and those other features and auxiliary systems which have been built into the ship in order to maintain essential services on board (IACS 2011).

The purpose of a classification society is to provide classification and statutory services and assistance to the maritime industry and regulatory bodies as regards maritime safety and pollution prevention, based on the accumulation of maritime knowledge and technology. The different classification organizations have their own and not identical rules (e.g. DNV 2013 or DNV-GL 2014).

Any modifications on board of a classed ship which deviates from the approved drawings or cause alterations of previously approved documents are regarded to be a conversion of the ship. Such modifications normally do have effect on the validity of class and in addition also on the statutory certificates issued by the classification society on behalf of the flag State Administration or by the flag State Administration itself. In so far such intended modifications are to be planned well in advance in order to maintain validity of class or validity of the corresponding statutory certificates, or even to ensure the issue of new additional statutory certificates which might be required after conversion.

The tasks and roles of the classification society and flag depend very much on the flag. Usually, the flag accepts the results of the investigation of the classification society, sometimes the flags partly check the modifications themselves.

For example in case of Iceland, no major modifications may be made to a ship, such as enlargement of the cargo spaces or superstructure, replacement of the main engine or modifications which affect the ship's measurements, seaworthiness and stability, safety and/or facilities of the crew, unless approval has been given by the Icelandic Maritime Administration, or another party authorized by the Administration. Modifications shall be carried out under the monitoring of the Maritime Administration, and the same rules apply concerning monitoring and notification, as in the case of the construction of a new ships (IMA 2003).

Ships and associated equipment are subject to prescriptive regulations. This framework contains very narrow requirements, for example in terms of number components or maximum capacity. These provisions restrain further developments. One consequence is a delayed introduction of new developments because they are only permitted after the amendment of the normative document.

The so-called alternative design allows the use of solutions as long as the safety equivalence of the modifications can be demonstrated. It is important that the realization of the modification must be approved by the flag State. The process of applying the alternative design is described in Figure 4.

For that purpose the formal safety assessment (FSA) can be applied. FSA is described as a structured and systematic methodology for rule-making, aimed at enhancing maritime safety, including safety of life, health and protection of the marine environment and property, by using risk analysis and cost-benefit assessment (IMO 2013).

FSA can also be used as a tool to help in the evaluation of new regulations for maritime safety and protection of the marine environment or in making comparisons between existing and proposed improved regulations. The basic philosophy of the FSA is that it can be used as a tool to facilitate a transparent decision-making process. FSA should facilitate the development of regulatory changes equitable to the various parties thus aiding the achievement of consensus. Thus, FSA is seen as an alternative to the set of existing regulations.

The alternatives of performing a risk analysis are illustrated in Figure 5.

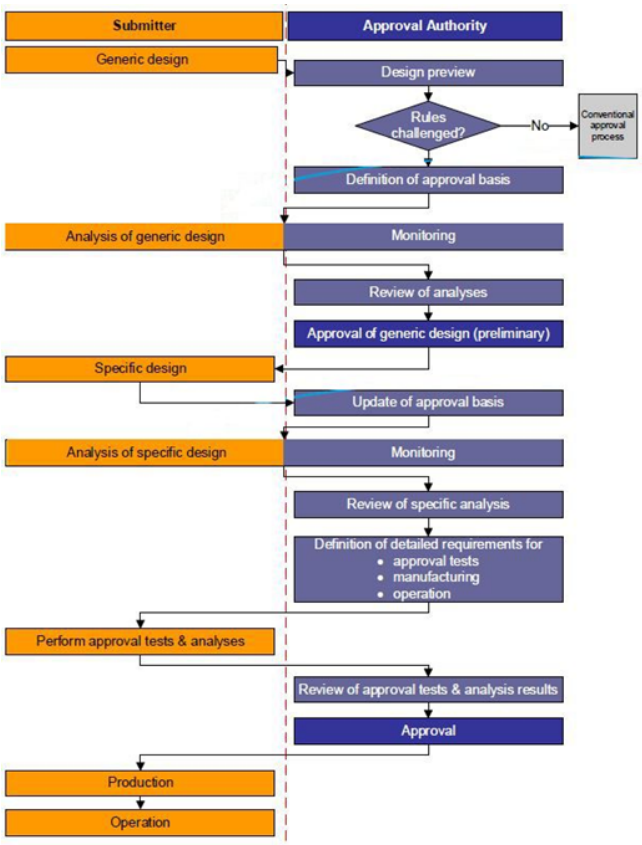

Figure 4. Alternative design.

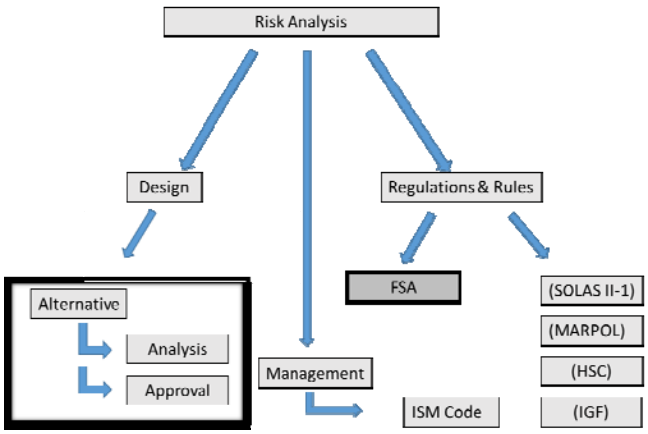

Figure 5. Risk-based methods in the maritime industry.

In addition, FSA provides a mean of being proactive, enabling potential hazards to be considered before a serious accident occurs (e.g. Zaman et al. 2015). However, in a recent review on the FSA (Psaraftis 2012) expresses a need for scientific discussion in the maritime domain about a number of fundamental issues concerning the FSA.

5 COMPARISON OF THE APPLIED APRROACHES IN THE DIFFERENT TRANSPORT SYSTEMS

The comparison of the three different transport systems shows that in the area of railways and aviation a European regulation describes the framework for the implementation of modifications. Concerning modifications in maritime transportation, there does not exist a comparable European regulation, while there are international guidance notes and general rules from different organizations like the American Bureau of Shipping (ABS), the International Maritime Administration (IMA) and also from the International Association of Classification Societies (IACS). The classification societies are an essential element within the assessment of modifications in maritime transportation. However, the responsibilities of the classification societies and the further requirements for the implementation of modifications depends on the flag of the ship and national regulations.

Furthermore, the comparison points out that all three approaches contain an explicit or implicit definition which modifications are relevant. Within the approach of European railways the proposer has to check, if the change falls within the scope of the CSM regulation and in the ongoing if the change is safety relevant. In this context, repairs do not fall within the scope of the regulation, if they are only the application of well-known measures or the substitution of faulty components. In the area of maritime transportation, repairs are also not considered to be a modification respectively a conversion, if the repair is implemented in accordance with approved documents and drawings. The conversion in turn is any modification which deviates from the approved drawings, although this definition has no general validity and also depends on the flag of the ship. In the area of European aviation, the regulation distinguishes between repairs and changes and the term repairs is explicitly defined within the given regulation while changes are only implicitly defined by the provisions within Subpart D (EC 2012). In contrast to maritime transportation and European Railways, also major repairs require some kind of risk analysis while for the implementation of minor repairs comparable to the other two transport areas generally accepted practices and QM-procedures have to be applied.

Regarding the assessment of the modification itself, all three areas are using different approaches. While basis elements of the consideration within the area of European railways are the experience with the implementation and further qualitative elements like the monitoring and the reversibility of the change in combination with risk-based considerations, within the other two approaches such criteria do not have any explicit relevance for the assessment. Although the use of new technology often result in major changes, proposed changes in the area of European aviation are classified regarding their influence on safety relevant elements like the mass, balance or further influences on the airworthiness. In this context, also the extent of the change has an influence on the final classification.

Also within the assessment of modifications in maritime transportation, the distinction between a major and a minor conversion is done by the consideration if any substantial aspect of the ship will be altered. Additionally, the extent of the modification and if it has an influence on the whole ship or, in contrast, only a limited influence on one certain component like the engine is relevant for the classification. However, the regulations within the area of European aviation are much more restrictive

since the influence of the proposed change on the certification specifications has to be taken into account for the classification of the change. One connecting element between the procedure in the aviation area and the CSM approach is the consideration of previous changes in the same area as the proposed change which were not classified as major respectively significant changes. In this case, the cumulative effect may result in a major respectively significant change such as a repeated discrete increase of speed by two per cent.

The purpose of the different approaches is to classify the proposed modifications within each transport system in order to determine the required proceedings for the safe implementation. For this purpose, the CSM approach has three different categories: changes which are not safety relevant or which do not fall within the scope of the CSM regulation, changes which are safety relevant and not significant and changes which are safety relevant and significant. Whereas only significant changes require the application of the harmonized risk management process with participation of an Independent Assessment Body. Safety relevant but not significant changes allow the application of own safety procedures without any independent assessment neither for the classification of the change nor for the chosen risk management process and its results. In contrast, the approach within the aviation area distinguishes between repairs and changes and possesses the three categories standard, minor and major within both groups. Furthermore, the major change is subdivided into substantial and non-substantial changes and some national authorities like the Irish Aviation Authority (IAA) additionally differentiates non-substantial changes into two subcategories, significant and not significant modifications to a type design (IAA 2010). In this context, only standard changes and repairs in the aviation area do not require a participation of the authority or an approved organization. All types of minor or major changes and repairs in turn have to be classified and approved by the EASA or a certified organization whereas major changes and major repairs always include some form of risk assessment. This aspects illustrates the restricted room for maneuvers concerning the assessment and the implementation of modifications in this area. Considering maritime transportation, modifications in this area either meet the definition of a conversion or not. Conversions in turn are classified into two groups, normal and major conversions, which may have an effect on the validity of class and the statutory certificates and normally require a participation of the classification society. Depending on the flag of the ship, the results of an assessment of such a classification society may be accepted or a participation of the national authority is required. In addition, some flags do not permit any major conversions without previous authorization by the authority or an authorized organization. Therefore, the level of participation of the authority depends on the flag of the ship but it is obvious that the regulations in this area are less restrictive than the regulations in the area of European aviation and give more room for maneuvers to the proposer.

6 CATEGROIZATION AND ASSESSMENT OF MODIFICATIONS IN NUCLEAR INSTALLATIONS

The nuclear technology is not monitored by European or other international authorities. The licensing and supervision of nuclear installations is perceived by the respective national authorities. However, the International Atomic Energy Agency provides fundamental principles, requirements and guidance with respect to nuclear safety which is not legally binding. One safety guide regarding classification of structures, systems and components (SSCs) has been recently issued (IAEA 2014).

At European level, so-called safety reference levels have been defined by the Western European Nuclear Regulators' Association which were recently updated (WENRA 2014). These reference levels should be adhered to by all member countries of the European Union (EU). In Part G of these reference levels, the safety classification of SSCs is described. The goal is to identify all safety related SSCs and to classify them according to their importance for safety. Part Q reflects modifications to a nuclear power plant (NPP) and it is requested that no modification degrades the plant's ability to operate safely. National regulations and international agreements are supplemented by a directive of the European Commission (2009b) which the EU members have to implement into the national law.

The licensing and supervision of nuclear installations in Germany is the responsibility of the Federal States (Länder) who are subject of expediency supervision of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB). In addition to the German Atomic Energy Act (Atomgesetz – AtG) (2013), there exist several national requirements which have to be considered in the approval and supervision process of nuclear facilities. A comprehensive update of the German sub-legal nuclear regulations has recently been issued (BMUB 2015).

Basically, each NPP in Germany must have a valid operating license. An essential part of this approval is the condition of the AtG to show all planned modifications (plant, operation and organization) to the competent authority and to examine their safety relevance. Significant modifications of systems according to § 7 AtG are subject to approval by the supervisory authority. The implementation of authorizations below this level is subject to a graded supervisory control depending on their safety significance.

The approach in nuclear technology is that all important equipment of a NPP are classified in terms of their safety significance, accompanied by respective requirements and specifications. The procedural rules for the treatment of modifications are regulated in operating manuals which are specific for each NPP and part of the approval of the authority to start/continue the operation of the NPP. Moreover, also modifications of the organizational structure or reduction of personnel are part of the process.

In the following, the procedure to evaluate modifications in the Federal State of Baden-

Württemberg is exemplarily described because this Federal State has developed a concept for regulatory supervision of NPPs - the last version is issued last year (UM BW 2013) - and a supervisory manual (UM BW 2011) with a separate detailed chapter describing the regulatory plant modification procedure (LEÄV) anticipating the safety requirements for NPPs (BMUB 2015). In this manual of Baden-Württemberg modifications are subdivided into three categories, designated as category A, B or C where A contains the highest requirements.

Figure 6 shows the procedure how to categorize modifications. In a first step, it must be considered whether the proposed modification relates to equipment which is subject to the AtG. In that case it must be examined whether this modification is a modification in the legal sense. If yes, the modification falls into category A.

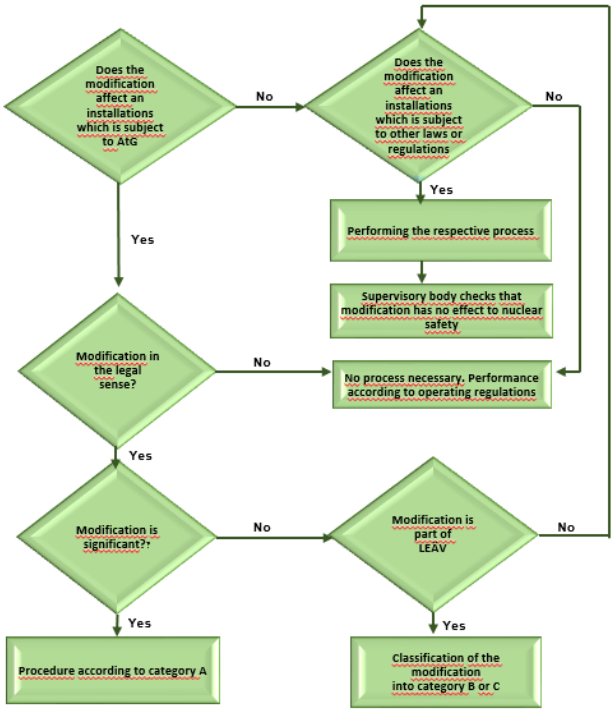

Figure 6. Procedure of categorizing modifications of equipment in NPPs.

One example is a modification which is not of nuclear relevance but requires other approval, e.g. by the respective building authority.

Otherwise, it must be checked whether the modification is subject to the uniform modification process. In this case, the modification falls into the category B or category C depending on the type of modification: is it only an exchange by equivalent equipment (components or systems) or leads the modification to a deviation in the approved specification. In the first case it would be a modification of category C, in the second one a modification of category B. In the following it is explained which procedure depending on the classification of the modification in one of the three categories is required according to (UM BW 2011).

Category A: If the modification belongs to category A, an authorization procedure is required by § 7 of the AtG and a permit application has to be submitted by the licensee to the supervisory body. The licensing procedure is conducted in line with the Nuclear Licensing Procedure Ordinance (2006). In addition, a probabilistic assessment is required to check the influence of the modification on the probabilistic safety analysis (PSA). It must be explained why the proposed modification has no effect on the PSA.

One example is the request for changing the license pursuant to § 7 AtG for the further development of the organizational structure at various nuclear power plant sites run by the same company.

Category B: If the modification belongs to category B, it must be supervised by the authority under § 19 of the AtG. A notification of the planned modification must be submitted by the licensee to the supervisory authority. The implementation of the modification can only take place if the supervisory authority has provided its written supervisory opinion that the proposed modification is seen from the perspective of the supervisor as "without any concern or not subject to licensing." An example is the dismantling of the wall hydrants in a building; as part of this planned modification hydrants have to be taken out of service and dismantled and portable fire extinguishers have to be installed. This is a modification of technical equipment and requires a modification of the operating manual.

The supervisory authority and the technical support organisation monitor and accompany the implementation of the planned modifications. In addition, a probabilistic assessment is required, as in case of a modification of category A showing the influence of the modification on the PSA. It must be explained why the proposed modification has no effect on the PSA.

Category C: If the modification belongs to category C, it must be monitored by the authority under § 19 of the AtG. An examination of the modifications in category C by an expert according to § 20 of the AtG is required. The implementation of the modification can only start after the expert has finalised his supervisory report and the authority does not make any objections until the modification starts. It is, however, no probabilistic evaluation required as in categories A and B.

An example is the replacement of a fluid level sensor including evaluation equipment. In the frame of this modification a level sensor is replaced because no spare parts for the existing device were available but an equivalent configuration is available on the market; this is seen as a minor modification of technical equipment and the operational manual.

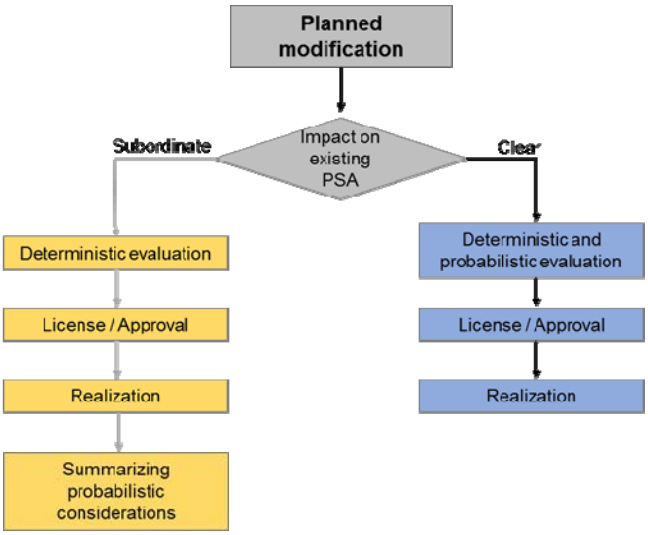

Figure 7. Categorization of modifications with expected risk relevance

The categorization of modifications with expected risk relevance is illustrated in Figure 7 above where a subordinate or a clear impact on the existing PSA is expected.

Modifications that are not subject to the procedure described above are performed by the operator according to its internal written operating procedures without participation of the authorities and experts. The supervisory authority will perform random checks based on the documentation provided by the operator, if the modifications are correctly classified.

7 CONCLUDING REMARKS

The comparison in Section 5 has illustrated the fundamental differences between the approaches and regulations of the three different transport sectors. Firstly, this affects legislation and supervision, e. g. if national or European institutions are responsible. For both, the area of European aviation and the European railway system, the applicable requirements directly result from European regulations. In contrast, in the area of maritime transportation, the responsibilities of the internationally active classification societies depend on the flag of the ship without the existence of an European legislation. It also depends on the flag, if in the case of an intended modification the results of the investigation done by the classification society are accepted or if the flag and its authorities check the modifications and the results of the investigation. The consideration in Section 6 has shown, that also modifications in the nuclear sector are not controlled by an European regulation, whereas the European legislator has provided some effort to create a common framework in nuclear safety as a reaction to accidents at the NPPs of Fukushima-Daiichi in 2011.

There are also fundamental differences regarding the considerations within the approaches. While the experience of the organization with the implementation of the change and further qualitative criteria are an essential part of the assessment within the CSM approach, these aspects do not have explicit relevance within the other approaches. This means that the classification of changes within the area of European railways depends not only on the change itself but also on the organization and its experience. On the other hand, basis of the approach which is used within the nuclear area are deterministic and risk-based considerations, for instance, if any possible influence by the modification on the PSA can be excluded. An extensive comparison of the approaches used in European railways and in European nuclear safety is discussed in (Petrek & Berg 2014). Also the approaches in the area of European aviation as well as in the area of maritime transportation use such a risk-based consideration without any qualitative aspects. However, the discussion in the previous sections has shown that also these three risk-based approaches are not identical but have fundamental differences with regard to their structure. This applies, for instance, to the different number of categories used for the classification of the modifications within each method as well as to the degree of participation of the authority. It also becomes obvious that there is no common definition neither for the term change nor for the term repair and how to handle repairs varies between the approaches. Additionally, there are major differences between the further process required on the basis of the final classification of the modification and, therefore, also between the room for maneuvers within each approach. The partially significant differences within the management of modifications and changes between the different technology sectors raises the question if a harmonization of the process and approaches could be reasonable. This applies in particular to the general question, if the experience of the proposer with the modification and its implementation should have any relevance within the assessment and, in addition, if the further differences described and analyzed within this paper are acceptable against the background of similar tools and fundamentals used for the demonstration of safety within the different technology sectors.

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