

APPROACH TO A SUPERVISION REGIME AFTER THE ISSUE OF A SAFETY AUTHORISATION

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SUMMARY

With regard to constructional and building installations the German national safety authority “Federal Railway Authority” (Eisenbahn-Bundesamt - EBA) is setting up a procedure to

- evaluate the effectiveness of maintenance-relevant SMS-processes based on object- and organisation-sensitive monitoring,
- demand remedy for detected shortcomings within these processes, and thus
- stimulate continuous improvement as an impetus for the reassessment of a safety authorisation.

In 2003 EBA started to develop a target process to be met by maintenance regimes.

By using a generic procedure EBA checks in how far IM's maintenance regime complies with this target process. The procedure defines a chronological sequence of steps which must be taken to meet the essential requirements of the maintenance process. This process is independent from the respective kind of installation.

Essential requirements can derive e.g. from applying safety-relevant technical rules, specifications and operational instructions, etc.. If such a requirement is not fulfilled the respective process step has failed.

EBA attends object-sensitive inspections in order to evaluate, on basis of a statistically sufficient sample, in which steps of the procedure shortcomings are detected most frequently. Steps in which failures are identified most frequently are the ones which must be deemed as organised less robust.

The consideration how early significant failures occur within the course of the process in conjunction with the failure rate provides an impression of the robustness of the process. This offers EBA the opportunity to estimate in which step of the process the IM organisation should take appropriate measures to make its process more robust. Thereby EBA can identify shortcomings and measure the integrity of the IM's maintenance processes, If used as element of supervision the findings can contribute to continuous improvement of the whole IM's maintenance regime.

In addition, this presentation points out how EBA targets its activities at the interface between safety authorisation and supervision according to Commission Regulation (EU) No. 1077/2012.

INTRODUCTION

Pursuant to Commission Regulation (EU) No. 1077/2012 the supervision regime of national safety authorities also comprises the verification of an orderly risk management, compliance with appropriate safety rules and the evaluation of the effectiveness of the operator's SMS – at least as those Infrastructure Managers (IM) and Railway Undertakings (RU) are concerned, which need a Safety Authorisation or Certification.

This remit mirrors monitoring activities which IMs and RUs are obligated to according to Regulation (EU) No. 1078/2012, in order to ensure duly accomplishment of the processes and effectiveness of their SMS.

Deriving from Commission Regulations (EU) No. 1158/2010 and 1169/2010 together with underlying Railway Safety Directive 2004/49/EC a SMS also has to comprise provisions for an orderly maintenance regarding control of risks, continuous improvement of the SMS and compliance with appropriate safety rules.

Supervision in line with Regulation (EU) No. 1077/2012

Pursuant to Art. 5 of Reg. (EU) No. 1077/2012 supervision and assessment of IM's/RU's SMS in the course of a Safety Authorisation / Certificate have to be arranged as interacting activities by the national safety authority. Findings from the one activity shall be mutually used for the accomplishment of the other.

Checking of the orderly accomplishment of obligatory safety rules and procedures which have to be duly incorporated in the SMS is one of the essential elements for the assessment of SMS-effectiveness.

It is characteristic for management systems that they specify operational sequences as processes, which have to comply with existing essential requirements. Essential requirements and basic elements of a SMS are laid down in Art. 9 (2) and (3) in conjunction with Annex III of the Railway Safety Directive 2004/49/EC.

This also comprises

- the implementation of control measures regarding relevant risks deriving from operation (Risk Control Management - RCM) and
- the obligation to continuous improvement of related processes and procedures (Continuous Improvement Process - CIP).

Deriving from the latter, processes and procedures need not be perfect from the outset. However, potential shortcomings must be duly detected by monitoring and supervision and rectified by measures of process improvement.

The effect of these measures must be monitored, respectively supervised.

Regulations (EU) No. 1077/2012 and 1078/2012 stipulate that this has to be done in a risk-based manner. Activities and measures must be prioritised appropriately, in order to ensure continuous improvement of the processes and their duly implementation in terms of SMS-safety performance.

Thus, the prerequisites regarding monitoring and - to some extent - supervision are determined:

- It is not necessary that monitoring and supervision activities constantly comprise all aspects of the SMS.
- However, these activities must focus a risk based approach and factors deemed essential for safety performance must be considered.
- Identification and management of the relevant risks arising from operation have to be embedded into the RCM.
- These factors have to be measurable through appropriate safety indicators and targets in order to make safety performance assessable.
- By means of threshold criteria risk control mechanisms shall facilitate the identification/prioritisation of processes and procedures whose performance must be improved.

Evaluation of safety performance and effectiveness of SMS

According to the CSM-regulations the effectiveness and safety performance of a SMS is essentially ensured through the application of the RCM by the railway organisations.

Thus, railway operators implement common safety indicators (CSI) and targets (CST) in order to control relevant risks. On the one hand these CSI and CST are defined in EU-regulations and directives and on the other hand these are proprietary indicators/targets for controlling of processes.

Additionally, there are mandatory technical rules (legal provisions in conjunction with standards, specifications and regulations) which cover the national safety-level and specific infrastructure related requirements. This also includes those regulations and codes of practice which constitute safety-relevant provisions.

Measures to ensure that these safety-provisions are met by appropriate procedures in the SMS are laid down in the specifications of Regulations (EU) No. 1158/2012 (ANNEX II, i.e. criteria B and ANNEX III, i.e. criteria C.) and 1169/2012 (ANNEX II, i.e. criteria B., V. and W.).

Assessment of safety performance in these cases does not primarily imply the consideration of operator's RCM-procedures but the evaluation if mandatory technical rules are complied with or not.

In other words supervision focuses the following question: does the SMS provide that these measures are applied through robust processes and comply with the requirements or are safety targets set by mandatory rules met too rarely?

No SMS can permanently guarantee perfect accomplishment of processes. Thus, it makes sense to assess the robustness of processes by a statistical approach. Therefore, a supervision regime must be installed that allows to evaluate the accomplishment of essential process steps - based on a sufficient number of samples. Moreover, it has to indicate in which steps of the procedure shortcomings are detected most frequently.

With regard to railway infrastructures correct construction and maintenance of such installations are key factors for safety. If installations get into a state or condition (wear and tear, end of service life, damage, etc.) and therefore do not comply with safety standards any more the extent of operation has to be adjusted accordingly – up to replacement, blocking or restricted use.

Hence CSM regulations and the Safety Directive 2004/49/EC stipulate that operator's SMS must ensure compliance with relevant maintenance requirements. However, there is no provision stipulating that maintenance proceedings must be explicitly specified as one or more processes. Nor does their correct application obligatorily have to be subjected to controlling as a designated part of the risk management in place.

Railway supervision in a notably rule-based environment

As the national safety authority also has to check the effectiveness of the operator's SMS and the national level of safety performance there is a need for tools which facilitate the assessment of orderly maintenance and safe operation through appropriate evaluation criteria.

As already mentioned the operator's organisation units are not obliged to set up explicit maintenance processes and corresponding controlling-tools in their SMS. However, it is necessary to install SMS-proceedings which comprise regulation- and risk management-compliant specifications and trigger a CIP as occasionally necessary.

Hence, it deems appropriate to determine a generic target process of maintenance in order to measure individual SMS-effectiveness and overall-safety performance, as well.

Maintenance standards for railways in Germany are specified in technical codes of practice to a considerable extent.

Closer consideration discloses that the maintenance proceedings mentioned therein follow a pattern which facilitates the definition of this generic target process and the relevant steps.

A variance analysis can be used to find out in how far the defined steps are really taken in the course of the maintenance process. This provides the opportunity to evaluate the robustness of the SMS-provisions in order to ensure that the procedures meet the essential requirements and their adequate fulfilment.

Standard DIN 31051:2012-09 (Grundlagen der Instandhaltung – Fundamentals of Maintenance) distinguishes maintenance into the four basic measures of servicing, inspection, repairs and improvement. In the context of safe operation only the elements inspection and repairs are relevant for further consideration.

Inspection – in this respect - means the appraisal if an installation is in a safely operable state, suitable for the actual or intended use plus the indication of diagnostic findings relevant for further use.

Repairs means all actions taken until an installation is restored to full serviceability again.

Pursuant to German Railway Construction and Operation Act (Eisenbahn-Bau- und Betriebsordnung – EBO) "... railway facilities and rolling stock have to be in a condition which meets the requirements of public safety and order. These requirements are deemed to be fulfilled if railway facilities and rolling stock comply with the rules of this Act and, as far as this Act does not contain explicit provisions, with the recognized codes of practice." (section 2 subsection 1). "Derogation from codes of practice is permitted, if at least the same level of safety as ensured by the codes of practice is evidenced." (section 2 subsection 2).

If necessary repairs cannot be realised or accomplished in due time, compensating interim measures (restricted use, placing out of service, additional checks, etc.) have to be set up in order to ensure safety.

Thus, the three basic elements of a target process of maintenance are outlined as follows:

- (1) Inspections of installations to meet underlying requirements,
- (2) detected derogations from targeted service conditions leading to choice and accomplishment of appropriate repair measures,
- (3) choice and conduct of remedial or operational interim measures necessary until full serviceability is provided by the repairs.

Due to the chronological sequence no. (1) is defined as process I and no. (2) and (3) are defined as process II in the following course.

Coming from these partial processes criteria are needed in order to develop the essential steps which constitute an orderly, measurable target process of maintenance. In order to characterise the process classification and evaluation criteria are used.

To classify criteria for accomplishment diagnostic findings and documentation of maintenance measures are applied.

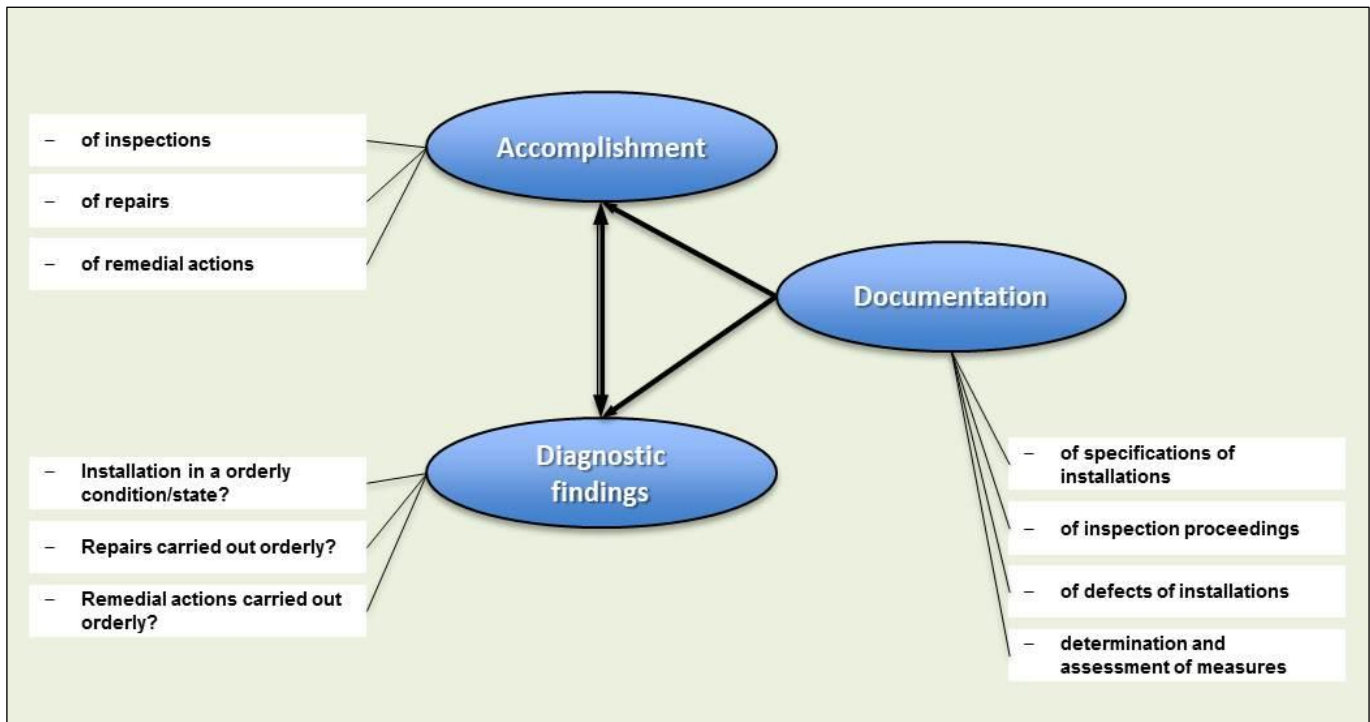


Figure 1: Classification criteria for the maintenance process

Evaluation criteria for the conduct of tasks derive from the questions "If?", "When?" and "How?".

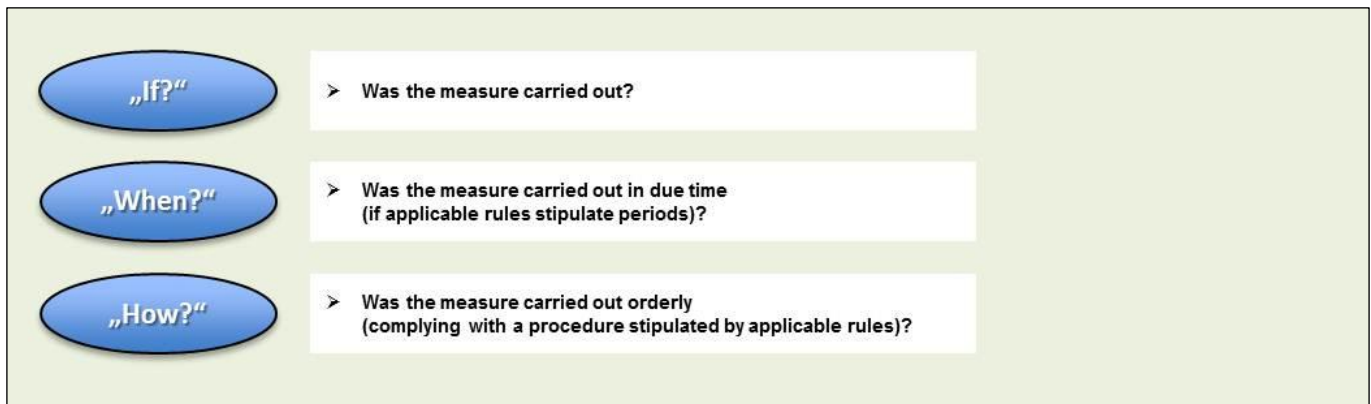


Figure 2: Evaluation criteria for the conduct of tasks

Classification and evaluation criteria can be combined.

Setting up reasonable combinations and structure them according to their chronological sequence, the relevant issues as expressed by figure 3 are revealed.

This procedural framework might be implemented into maintenance regulations as follows:

- relevant specifications of the installations must be available, (process step I.1)
- inspections have to be carried out correctly, (process step I.2)
- eventual defects have to be ascertained correctly, (process step I.3)
- all information relevant for repairs must be available, (process step II.1)
- adequate necessary remedial actions must be taken, (process step II.2)
- repairs have to be performed correctly. (process step II.3)

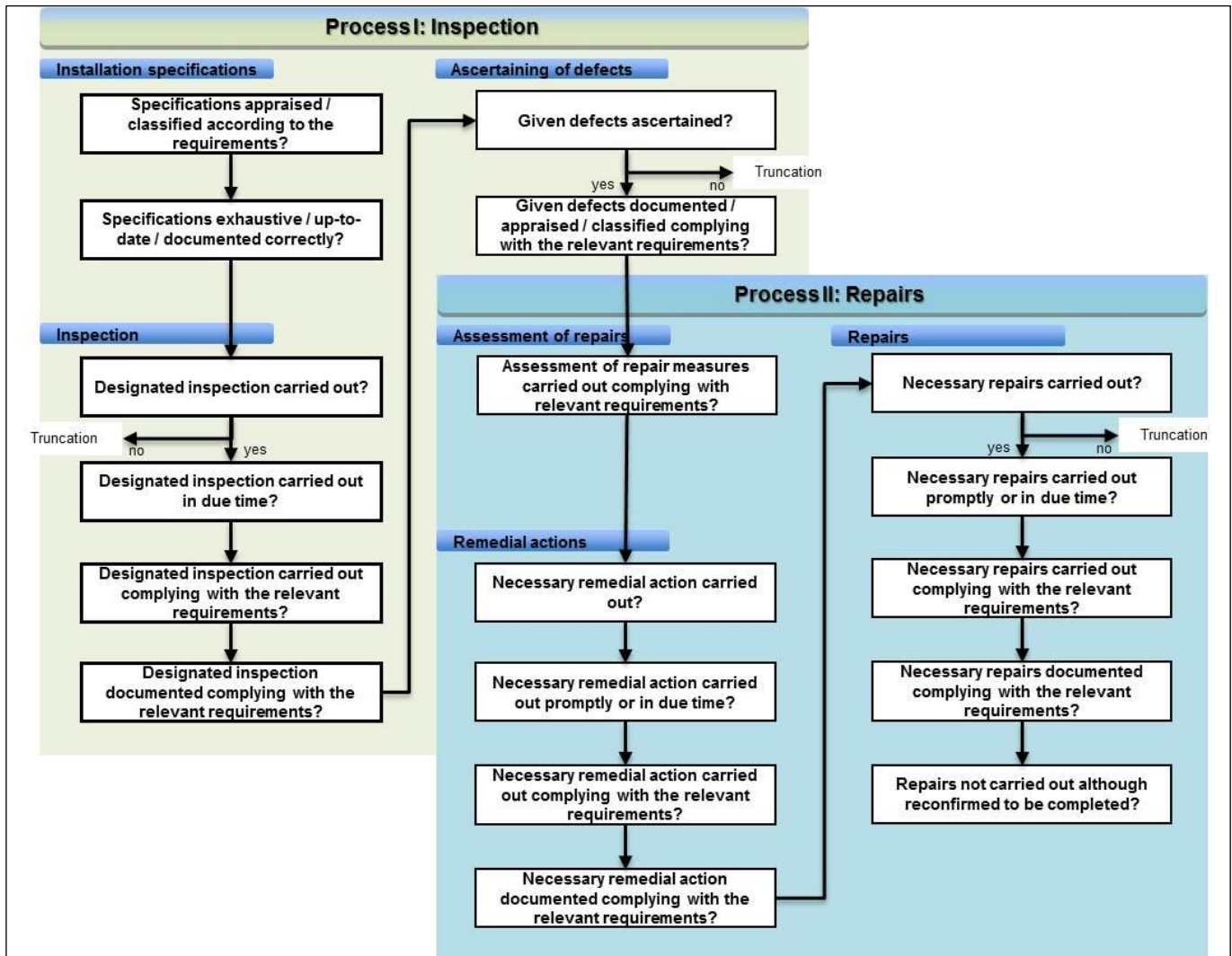


Figure 3: Chronological sequence of process steps essential for maintenance

The sequence with all steps evolves as follows:

Process I – Inspection

I.1: Specifications relevant for installations

I.1.1 **Applied specifications of installations not appraised / classified complying with the relevant requirements**

I.1.2 **Applied specifications of installations not exhaustive, up-to-date or documented incorrectly**

I.2 Inspection

I.2.1 **Designated inspection not carried out**

I.2.2 **Designated inspection not carried out in due time**

I.2.3 **Designated inspection not carried out complying with the relevant requirements**

I.2.4 **Designated inspection not documented complying with the relevant requirements**

I.3 Ascertaining of defects

I.3.1 **Given defects not ascertained**

I.3.2 **Given defects not documented, appraised or classified complying with the relevant requirements**

Process II – Repairs

II.1 Assessment of repairs

II.1.1 **Assessment of repair measures not carried out complying with the relevant requirements**

II.2 Remedial actions

II.2.1 **Necessary remedial actions not carried out**

II.2.2 **Necessary remedial actions not carried out promptly or in due time**

II.2.3 **Necessary remedial actions not carried out complying with the relevant requirements**

II.2.4 **Necessary remedial actions not documented complying with the relevant requirements**

II.3 Repairs

II.3.1 **Necessary repairs not carried out**

II.3.2 **Necessary repairs not carried out promptly or in due time**

II.3.3 **Necessary repairs not carried out complying with the relevant requirements**

II.3.4 **Necessary repairs not documented complying with the relevant requirements**

II.3.5 **Repairs not carried out although reconfirmed to be completed**

Figure 4: *Generic target process of maintenance*

Through these 18 sequential steps the generic target process is determined and applicable to all kinds of installations and inspections.

Process-related supervision in the field of civil engineering, permanent way and structural engineering

Due to its responsibilities in the field of supervision EBA undertakes monitoring activities pursuant to the General Railway Act (Allgemeines Eisenbahngesetz - AEG) and the Federal Railway Traffic Administration Act (Bundeseisenbahnverkehrsverwaltungsgesetz – BEVVG).

Regarding civil engineering, permanent way and structural engineering EBA specifies this task in its administrative regulations VV Überwachung (organisational framework for supervision) and VV Eisenbahnaufsicht (supervision and monitoring activities).

IMs carry out installation inspections on basis of technical specifications. EBA undertakes regular object-sensitive monitorings by attending these inspections in a number of sample cases. Additionally, EBA also performs organisation-sensitive monitorings at the IMs as well as occasional monitorings are made after irregularities or hazardous incidents have occurred.

For IMs operating ample rail networks or areas of infrastructure, the sample of object- and organisation-sensitive monitorings (custom monitoring) shall provide a statistically reliable picture in how far maintenance organisations meet the requirements. At the same time the sample reflects the potential risk arising from the respective kind of installation.

If an infringement of a safety rule or regulation is detected an underlying deficiency within the process of maintenance is presumed. Then further monitoring must clarify which step(s) of the procedure has/have failed (process-related supervision).

Hence, whenever an infringement of a safety rule is detected the whole maintenance process is assessed with respect to the inspected installation.

The generic target process is used like a checklist. For each combination of kind of installation and inspection the number of the examined installations is recorded, together with the number of installations with detected infringements and of failed process steps as well. The results and informations of the monitorings are transferred into a database.

In addition to these findings process steps which derive from severe maintenance infringements are registered, as well. For that purpose a catalogue was developed for the field of civil engineering, permanent way and structural engineering which mentions case examples and explains when infringements must be regarded as a severe violation of safety standards.

This comprises cases where...

- an undesirable state of the facility or performance of operation is given, which deems to be avoided complying with the rules,
- due to deficiencies in the sequence of the process the following course of maintenance activities is impaired massively (truncation of the process),
- because of other reasons the actual safe condition of a facility is diminished objectively to an extent which demands for immediate remedial actions in order to ensure safety.

Severe infringements are always a real subset of safety-related deficiencies.

Infringements which are not per se categorised as severe are still safety-relevant but experience in these cases often shows that a notably larger potential of risks only has to be taken into account if a less likely concatenation of these circumstances occurs. Experience on accumulated potential risks to be taken into account should be covered through the RCM. So, the corresponding catalogue of severe infringements – which has been in force since January, 1st 2014 – is continuously adjusted to the experience made.

Experience gained through application and assessment of process-related supervision

Entering findings into a database enables almost any analysis but always under the precondition that the chosen field of consideration frames a sufficient sample.

It is possible to filter by area/kind of installations, regional areas of maintenance organisations and time periods of monitoring.

Standard reports are set up in annual or biennial intervals, for example, assessing installations by kind or combined by those technical rules, which regulate their maintenance following the same order.

Assessment of the robustness is done for each part (I and II) of the process separately. Each subprocess shows the proportionate scatter of the detected defects over the process steps.

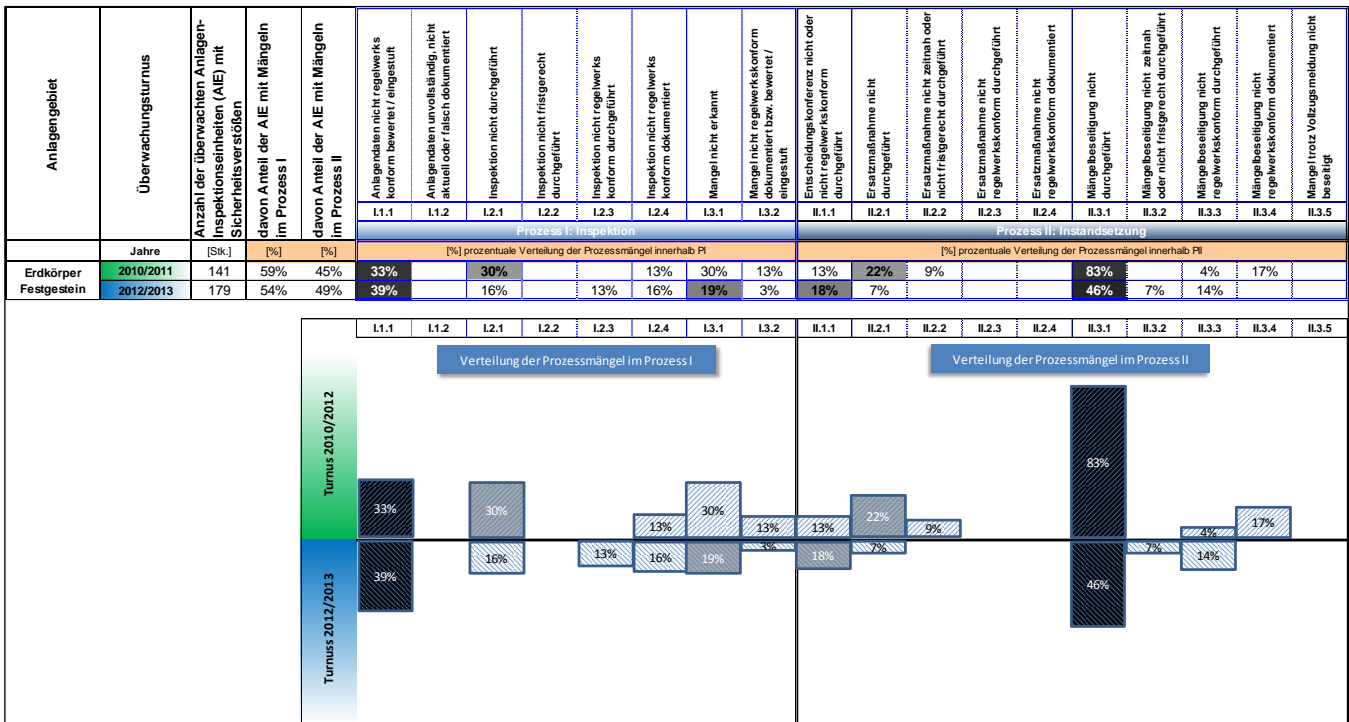
Anlagengebiet	Anzahl der überwachten Anlagen-Inspektionseinheiten (AIE) mit Sicherheitsverstößen		davon Anteil der AIE mit Mängeln im Prozess I		davon Anteil der AIE mit Mängeln im Prozess II		Anlagenarten																				
	[Stk.]	[%]	[Stk.]	[%]	[Stk.]	[%]	I.1.1	I.1.2	I.2.1	I.2.2	I.2.3	I.2.4	I.3.1	I.3.2	II.1.1	II.2.1	II.2.2	II.2.3	II.2.4	II.3.1	II.3.2	II.3.3	II.3.4	II.3.5			
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Eisenbahnüberführungen	322	63%	43%			23%									50%	45%	22%									88%	
Durchlässe	260	64%	49%			25%	37%								22%											61%	86%
Stützbauwerke	211	68%	47%	13%		46%									27%	13%										39%	91%
Erdkörper Festgestein	141	59%	45%	35%		29%						13%			29%	13%	15%		20%	10%						85%	
Erdkörper Lockergestein	229	88%	17%			13%	19%								21%	37%	27%		45%							82%	18%
techn. gesicherte BÜ	317	62%	58%			13%									87%											95%	
nicht techn. gesicherte BÜ	138	53%	68%			10%									90%											100%	4%
Gleise (*)	486	26%	78%			30%	31%	15%																		81%	14%
Weichen	397	32%	76%			23%	28%	18%										12%								91%	17%

Figure 5: object-related assessment of the findings – schematic representation of the scatter of detected defects within the maintenance process

Experience shows that every detected infringement of an applicable rule can disclose several deficiencies within the course of the maintenance process. The grayscale representation shows in which steps the process deficiencies occur most often, where findings differ or are similar across different kinds of installations.

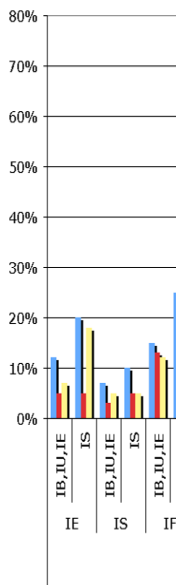
For the assessment it is assumed that a process is more robust the later infringements occur on average and the less process deficiencies are detected. Process deficiencies occurring most and second most often are the starting points for the considerations, in which steps shortcomings in maintenance procedures may exist and where IMs should start with remedial measures.

By comparing the results of different time periods of monitoring the tendencies in developing maintenance activities can be derived – especially whether continuous improvement can be achieved middle term.

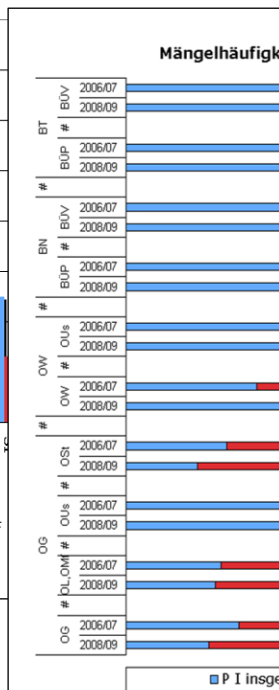


Mängelhäufigkeiten nach ausgewählten AA/ÜA:

■ gesamt ■ P I ■ P II



Turnusvergleich: Mängelhäufigkeiten nach ausgewählten AA/ÜA über P I und P II insgesamt



Turnusvergleich: Verteilung der Mängelhäufigkeiten nach ausgewählten AA/ÜA in den Teilprozessen

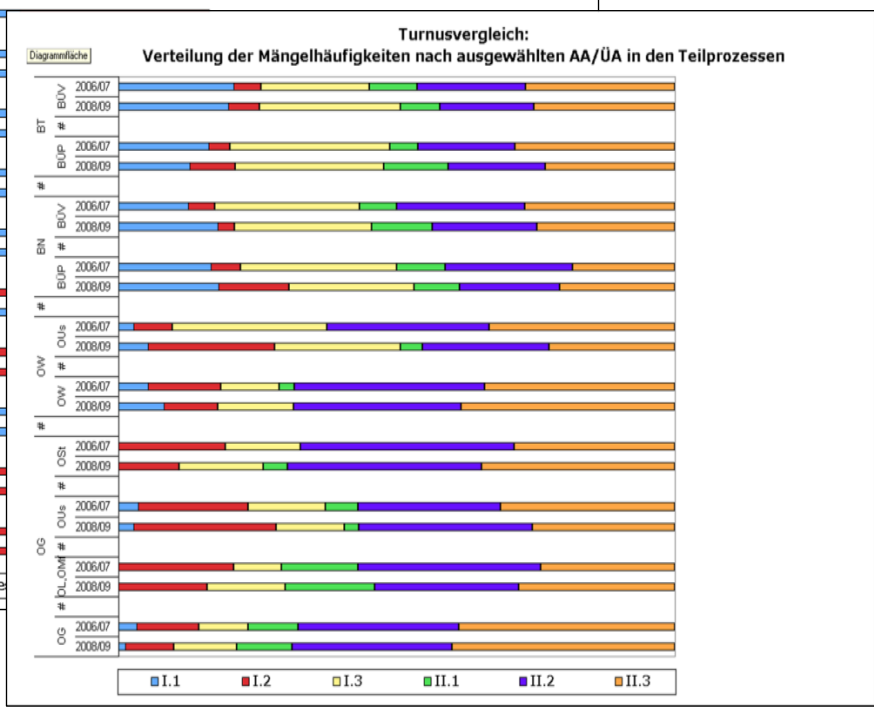


Figure 6: compilation of findings about process deficiencies, illustration of their development and further options of analysis - schematic representation

Findings are processed through database reports. These reports deal with the amount of deficiencies in the course of the process, the kinds of installations and severe infringements and the overall development.

Primary aim is to evaluate tendencies and to identify starting points for continuous improvement. Results and findings are frequently discussed with the IM's maintenance organisations which are urged to take measures in order to make their maintenance processes more robust in those process steps where most deficiencies occur. These commitments shall satisfy SMART-criteria (specific, measurable, achievable, realistic, time-related).

Success of these measures is monitored in the following turn.

Links between process-related supervision and assessment as part of a safety authorisation

The process-related part of supervision visualises where shortcomings and severe deficiencies occur most often - having regard to different maintenance organisations and different kinds of installations. As a result safety performance and development can be duly evaluated.

This generic target process can serve as mean to assess the performance of maintenance procedures for any kind of installation. Thus, it is independent from specific IMs' SMS-provisions. Interfaces to SMS exist in the requirements for adequate risk management and the obligation to ensure continuous improvement.

Frequent deficiencies, especially severe infringements, indicate which remedial measures must be taken by the IMs as part of their risk management in order to grant safe operation as required.

Dedication to continuous improvement is a challenge for IMs to permanently monitor compliance with safety requirements and remediate detected deficiencies by corrective actions. This is mirrored by supervision performed by the safety authority.

Regulation (EU) No. 1077/2012 provides further provisions for supervision activities:

- checking of the effectiveness of the SMS and its partial elements,
- supervision of the continued application of SMS after the issue of a safety authorisation or certificate,
- use of information and experience gathered during supervision activities for reassessing a SMS prior to the renewal of a safety authorisation / certificate,
- targeting of activities according to a supervision strategy and setting priorities in supervision plans.

EBA's supervision regime takes this into focus. In terms of civil engineering, permanent way and structural engineering the different supervision elements are depicted in figure 7 pursuant to VV EA.

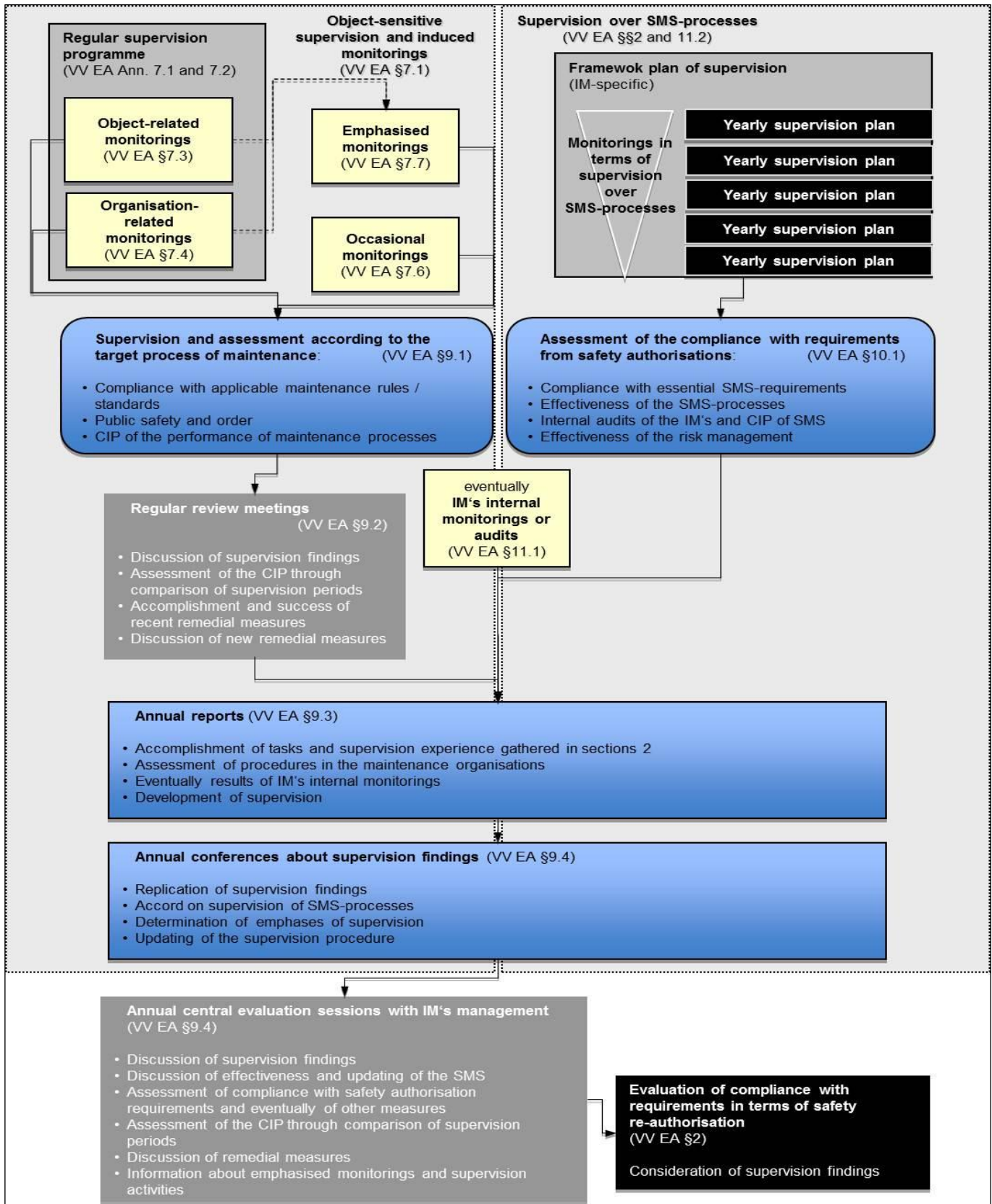


Figure 7: Elements of supervision in the field of civil engineering, permanent way and structural engineering

Explanation of the context:

- Occasional monitorings (induced externally):
They are carried out after irregularities or hazardous incidents are reported.
- Emphasised monitorings (induced internally):
They are carried out if evaluation or incidents indicate that there may be considerable organisational, operational or technical deficiencies in some sectors.
- Framework plan of supervision / yearly supervision plans:
As result of the safety authorisation assessment questions relevant for further supervision are arranged into a framework plan set up for the period of validity of the authorisation. From these questions supervision activities are drafted which are -depending of their given priority- gradually taken into annual plans. Points still open or with need for action that remained from the prior year are transferred into the updated plan. At the end of the authorisation's validity the fulfilment of the points in question and the success of the remedial actions become means to assess the subsequent safety authorisation.

Figure 7 above demonstrates that supervision comprises the two fields of "object-related supervision" (process-related custom monitorings + emphasised monitorings = regular supervision programme) and "supervision of SMS-processes" (IM-specific).

With respect to object-related supervision monitoring is evaluated at level of sections 2 by the regionally competent branch office of EBA. Process-related findings and experiences are discussed by these sections and the supervised maintenance organisations. This happens in regular review meetings at the end of the particular supervision cycle when the sample of the provided custom monitorings is complete.

Experience of sections 2 collected from monitoring and accomplishment of maintenance procedures on the one hand and from assessing requirements of the safety authorisation on the other hand are included in annual reports to be addressed to Division 21 at EBA-Headquarters.

They collect the results and inform about the findings of the IM's own monitorings (i.e. audits). Furthermore, they determine the strategy and the activities of subsequent supervision.

The annual plan and the activities are coordinated in annual conferences about supervision findings. Appraisal of the SMS effectiveness, safety performance and the CIP will be discussed in annual central evaluation sessions with IMs at management level. All experience is analysed and later on used for the assessment of the subsequent safety authorisation.

Hereby, all objectives and elements of supervision pursuant to Regulation (EU) No. 1077/2012 are implemented by VV Überwachung and VV EA in the field of maintenance.

Current conclusions demonstrate that process-related and SMS-specific supervision delivers substantial findings about shortcomings in maintenance and SMS-processes. It makes quality of procedures measurable and is suitable to deliver the governmental contribution to warrant SMS-effectiveness.

CONCLUSION

The supervision task of the safety authorities also comprises assessment of the safety performance of the IM's SMS.

Maintenance of installations which meets the requirements delivers an important contribution to safety.

Process-related supervision facilitates the assessment of accomplishment and performance of the relevant maintenance provisions determined in the SMS. This is carried out on basis of statistically sufficient samples at IMs which operate ample rail networks or areas of infrastructure.

This delivers insight where the most frequent and severe infringements occur within the course of maintenance and thus, where IM's remedial actions must start from in order to improve the processes. Where necessary this is claimed by the authority to facilitate continuous improvement of the SMS in terms of the IM's maintenance regime.

In combination with the other activities in the scope of supervision specified here the SMS-performance, the safety level and the effectiveness of the safety regulatory framework become measurable.