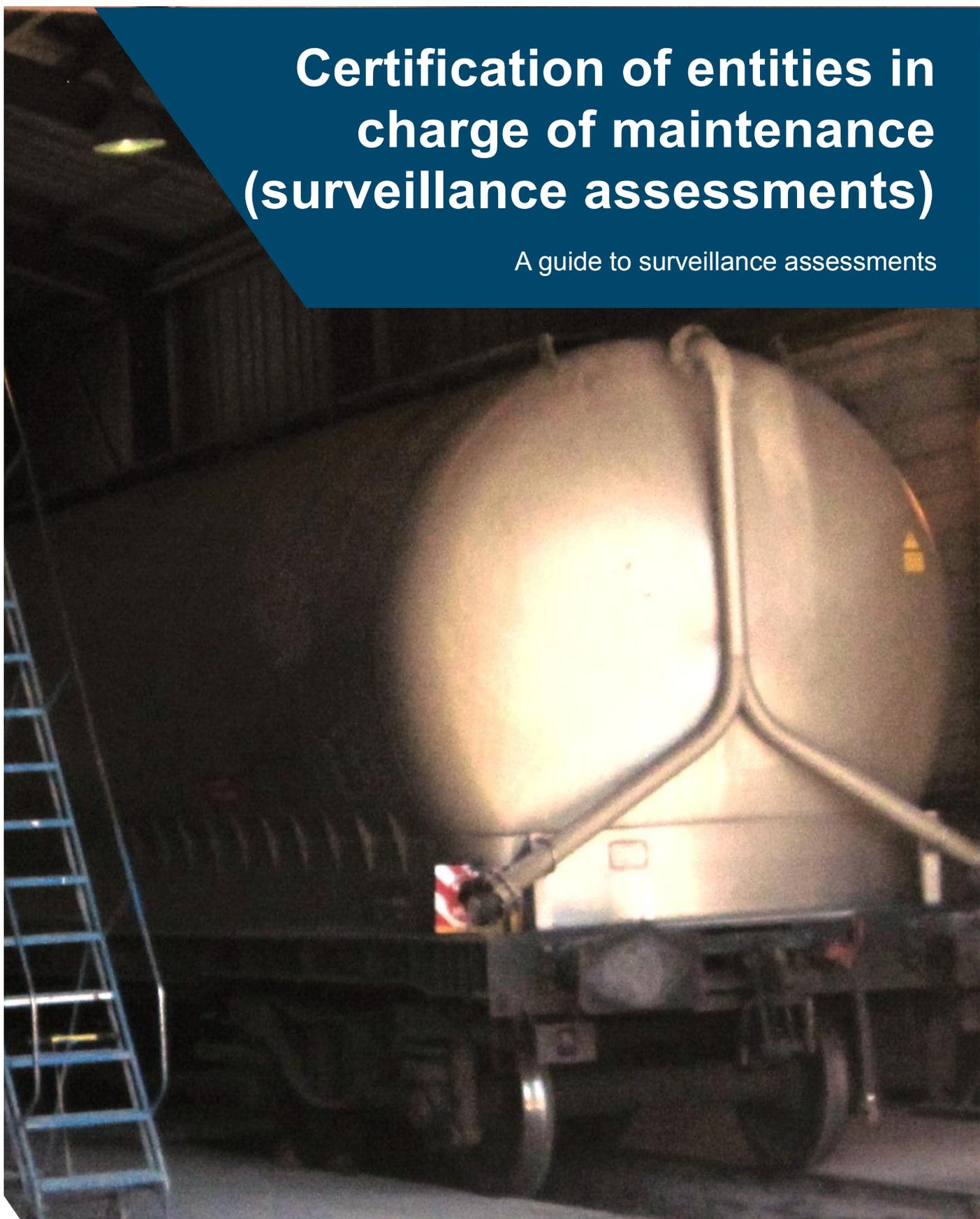


Certification of entities in charge of maintenance (surveillance assessments)

A guide to surveillance assessments



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This guidance is issued by the Office of Rail Regulation. Following the guidance is not compulsory and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Railway inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

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1. Surveillance assessments for certificated entities in charge of maintenance (ECM)

1.1 This manual outlines the process for surveillance assessments associated with the certification of entities in charge of maintenance (“ECM”).

1.2 The surveillance process will involve wherever possible the same assessment team that carried out the assessment on the initial application of the certified ECM.

1.3 The following ORR personnel will be involved during the surveillance assessment:

- Lead assessor (FOC team)
- Engineering assessor (RVNET)
- ECM certification process manager
- Head of Inspection (Railway Operators)
- Grade G in RSD’s Directorate Support Unit (DSU)

1.4 Surveillance assessments will comprise of:

- a review of previous assessments of the ECM’s activities;
- a review of the ECM’s annual maintenance report;
- a review of documents supplied by the ECM; and
- an on-site inspection.

2. Purpose of surveillance assessments

2.1 The purpose of carrying out surveillance assessments is to verify that the ECM still complies with the criteria set out in Annex III of the ECM regulation.

2.2 Surveillance assessments will be carried out on an annual basis over the validity period of the ECM certificate, which in most cases will be five years. In some cases, organisations newly taking on ECM duties may be issued with a certificate valid for a lesser period.

3. Annual maintenance report

3.1 Point I 7.4(k) of Annex III of the ECM Regulation mentions the submission of an annual maintenance report to the Certification Body, which is based upon activities of the management function. This report may also be requested by the National Safety Authority (NSA). The Annex does not specify the contents of the report. However, the contents suggested below have been established through collaboration between industry and the Office of Rail Regulation (ORR) in its role as Certification Body, and with reference to:

- Commission Implementing Regulation (EU) 402/2013 on the common safety method for risk evaluation and assessment (repealing Regulation (EC) 352/2009) (the CSM for risk assessment);
- Commission Regulation (EU) 1078/2012 on a common safety method for monitoring (the CSM for monitoring); and
- guidance from the European Railway Agency (ERA).

3.2 The checklist and table below can be used as a template for the report if desired. However, if the information is already covered in another format then this may be provided to the Certification Body.

3.3 The report should be proportionate to the size and nature of the business.

3.4 The annual maintenance report that is submitted by the ECM certificate holder should contain information on the following:

- progress towards closure of any issues outstanding from the certification process;
- summary of any non-conformities identified by the ECM's own internal review and audits;
- summary of information exchanged regarding defects and failures with other stake holders, e.g. NIRs;
- summary of NSA or other authorities' enforcement actions;
- summary of any formal investigations in which ECM activity has featured, e.g. RAIB;
- information on the ECM's experience of applying the CSM for monitoring and (from 21 May 2015, the CSM for risk assessment); and
- significant changes during the year related to the following as identified in the table below

Significant changes within the ECM’s business during the year:

Topic	Changed; Y or N?	Details of change
Legal ownership of the company		
Organisational changes affecting ECM activity		
Volume of maintenance activity		
Types of vehicles and quantities		
Types of facilities used for maintenance, e.g. now using mobile fitters, or now using workshops only		
Contractors now being used, or now not being used		
Competence systems, processes and equipment		
Maintenance and Maintenance Planning systems, e.g. changes in maintenance practises and documentation		

CSM for risk assessment

3.5 Point I(2.3) of Annex III of the ECM Regulation states that the ECM must have risk assessment procedures to manage changes in equipment, procedures organisation, staffing or interfaces, and to apply Commission Regulation (EC) 352/2009 (the CSM for risk assessment). Regulation 352/2009 will be replaced by Commission Implementing Regulation (EU) 402/2013 with effect from 21 May 2015.

3.6 Point Article 18(3) of the Regulation EU 402/2013 requires for ECM’s for freight wagons to include information about its experience of applying CSM in the annual maintenance report. This means that reports submitted after 21 May 2015 should contain information about the application of the CSM.

3.7 The CSM for risk assessment places duties primarily on the proposer of a change. Proposers are those in charge of projects who wish to implement a change to a technical, operational or organisational aspect of the railway system. When a proposed change has an impact on the safety on the mainline railway, the CSM places a duty on a proposer of change to decide, by expert judgement, the significance of a change based on six criteria:

-
- failure consequences;
 - novelty;
 - complexity;
 - the inability to monitor the change;
 - reversibility; and
 - additionality

3.8 If a change is regarded as significant, the risk management process described in the CSM should be followed.

3.9 Guidance on the CSM for risk assessment can be found on [ORR's website](#)

CSM for monitoring

3.10 Article 5(3) of the CSM for Monitoring requires ECM's to report in their annual maintenance report their experience of using the CSM. The CSM for Monitoring is directly applicable in each Member State and applies to all ECM's (as well as railway undertakings and infrastructure managers). An ECM needs to ensure that

- the risk control measures implemented on its contractors are monitored using the process in the CSM; and
- its contractors apply the same process through contractual arrangements.

3.11 The Rail Safety and Standards Board (RSSB) has produced a [short guide](#) on the CSM for monitoring.

Submitting the annual maintenance report

3.12 The report should be provided to the lead assessor approximately 4 weeks before the anniversary of the ECM certificate issue date and then on an annual rolling basis from that time (i.e. 12 months after submission of the initial annual maintenance report).

3.13 The annual maintenance report must be submitted in electronic format as agreed to the Railway Safety Directorate's Directorate Support Unit (DSU) (rsd.admin@orr.gsi.gov.uk) who will then forward onto the relevant assessors.

4. Planning the surveillance assessment

4.1 The annual maintenance report will form part of the process for selecting topics to be covered as part of the surveillance programme with the ECM.

4.2 For the first surveillance period, the assessment team will review the final assessment report from the initial application to see if the ECM needed to take any corrective actions post award of the certificate.

4.3 For future surveillance periods, the assessment team will ensure issues raised in previous surveillance assessments have been closed out in a satisfactory manner and within agreed timescales. If any issues remain open, these will be checked in the next available surveillance period.

4.4 In consultation with the engineering assessor, the lead assessor will make the final decision on which topics will be chosen for the surveillance assessment. A discussion will take place between both assessors as to how much detail will be required from engineering assessor when looking at the parts II – IV of annex III during their site visit.

4.5 The lead assessor will notify the ECM, of the topics that have been selected for assessment in the surveillance period. Where the surveillance activities include a site inspection, agreement should be reached between the assessors and the ECM as to when this is convenient for all parties. Depending on the availability of the assessors, separate visits may occur. The ECM will be notified of this as early as possible.

4.6 In addition to the topics chosen by the assessors using the above selection criteria, mandatory topics chosen that have cross industry interests may also be chosen. If mandatory topics are chosen, these will be notified in advance to the ECM.

4.7 Details of the assessment should be recorded on the surveillance assessment form and issued to the ECM once the Head of Inspection (Railway Operators) has agreed to scope of surveillance assessment.

5. Performing the surveillance assessment

5.1 The surveillance assessment will consist of a documentary review and / or site inspection.

5.2 The lead assessor will communicate how they wish to receive the documents; hard or electronic copy and advise the ECM of the site(s) the assessors wish to inspect.

5.3 The lead assessor will focus on the management function (part I) of annex III in the ECM regulation during their visit. The engineering assessor as part of their visit will cover parts II – IV of annex III in the ECM regulation: maintenance development, maintenance management and maintenance delivery functions.

6. Documentary Review

6.1 The ECM shall send to the assessors, the documentation requested in the surveillance assessment plan (unless it has been agreed in advance that documents will be examined during the site inspection).

6.2 The review is to ensure the documentation is relevant to the requirements for certification. The assessors should check that the procedures put in place by the ECM in its maintenance system are:

- compliant with Annex III of the ECM Regulation;
- established;
- documented; and
- reviewed regularly.

6.3 Relevant supporting documents include working instructions, forms, templates etc. The ECM may also provide any other documentation that it believes is relevant to demonstrating compliance with criteria such as audits from the ECM Service Provision Agreement (“ESPA”) or other industry schemes, etc. The size, complexity and nature of the organisation should be taken into account when carrying out the task.

6.4 If the assessors have concerns over the documentation presented, they may request additional documents to check that the ECM complies with requirements of Annex III of the ECM Regulation.

6.5 The documentary review form should be completed to show which documents have been reviewed and any comments / observations relating to the document should be recorded on this form. The form will be issued as part of the surveillance report and needs to be stored on Mosaic.

7. On-Site Inspection

7.1 On-site inspections will form part of surveillance assessments. Assessors will base their inspections on:

- issues highlighted in the annual maintenance report,
- findings from the initial assessment; and
- results from previous surveillance assessments.

7.2 In the event of any changes during the validity period of the certificate which:

- have been identified in the annual maintenance report;
- have been made known to the assessors; and
- could impact on the safe delivery of maintenance,

a site inspection is mandatory.

7.3 Inspections will take place on a number of selected sites during the surveillance programme over the certificate's validity period. This will depend upon the size and nature of the ECM's business and will represent the ECM's activities geographically and functionally.

7.4 If any major issues are found at a site during the initial assessment programme or surveillance periods, the assessors shall revisit the site concerned to inspect the measures put in place by the ECM to address them. This may be in the next surveillance period or earlier, depending upon the issues that are found.

7.5 An on-site inspection may involve interviewing selected members of staff on a site to ensure the documentation is in place and used correctly; (for example, working instructions, templates, check lists, etc.).

7.6 An on-site inspection should also provide an indication that the documents in place by the ECM are appropriate to the size and extent of activities undertaken.

7.7 Where an external site is to be inspected, arrangements should be made with the ECM and the external site in advance. The inspection of an external site should focus on how it meets the requirements of Annex III of the ECM Regulation. The assessors should ensure staff from the ECM accompanies them on the site visits.

7.8 We may take the opportunity to combine ECM surveillance activities with our on-going NSA role for supervising railway undertakings and infrastructure managers. If this happens, any findings should be recorded as part of the surveillance assessment programme.

7.9 Assessors are encouraged to produce individual site inspection reports as part of their visits as these may be required for use in future surveillance assessment periods.

7.10 If any general health & safety issues are found on-site requiring immediate attention, they should be notified to the site management team on the day and then by email at the earliest opportunity. The assessors should request that actions are put in place and implemented in suitable timescales with notification provided upon completion to the assessors.

8. Surveillance Assessment Reports

8.1 An assessment report will be issued to the ECM which explains the surveillance activities undertaken and will form the basis for a decision as to whether the certificate remains valid..

8.2 The template for the surveillance report will be similar to the initial assessment report although the documentary review form will now be an appendix to the report to avoid duplication of work in the main body of the report.

8.3 A draft report will be issued to the ECM within 15 days of the surveillance assessment concluding.

8.4 A meeting will be held with the ECM to discuss the report and agree timescales for addressing any issues raised within the report.

8.5 In addition, the engineering assessor may wish to produce for internal purposes, reports by individual Annex III engineering functions (parts II – IV).

9. Certificate Validity

9.1 Providing no major issues are found during the surveillance assessments, the certificate will remain valid as issued.

9.2 If there are concerns about the findings of the surveillance assessments, the assessors may discuss

- issuing an improvement plan to the ECM with appropriate timescales to close out actions assigned;
- limiting the scope of the certificate; or
- suspending or revoking the certificate.

9.3 The head of inspection (railway operators) should be notified at the earliest opportunity if these options are being considered.

10. Monitoring Surveillance Assessments

10.1 It is important that the assessment activities are monitored and tracked during the surveillance periods as they may form part of the surveillance assessments for future periods.

10.2 The ECM certification process manager will ensure surveillance assessments are carried out as per the agreed process.

10.3 The ECM certification process manager will work with the assessors in ensuring recommendations from surveillance assessments are recorded and tracked through to close-out or carried forward into the next period of surveillance.

11. Appeals

11.1 An ECM can appeal if the surveillance assessment programme results in ORR

- limiting the scope of its certificate;
- issuing an improvement plan it did not agree to; or
- suspending or revoking its certificate

11.2 Appeals should be sent, within 42 days of receipt of the decision, to the Secretary of State at:

Department for Transport,

Great Minster House

33 Horseferry Road

London

SW1P 4DR

11.3 Before the determination of an appeal, the Secretary of State will ask the appellant whether he or she wants to appear and be heard on the appeal. The appeal may be determined without a hearing if both parties (ORR and the appellant) do not wish to appear and be heard. However, if either party wishes to appear and be heard, they will have the opportunity to do so.

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