

Dutch Accreditation Council (RvA)

Shadow assessments

Document code:

RvA-T040-UK

Version 2, 18-12-2017

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A current version of the Explanatory is available through the website of the RvA. (www.rva.nl).

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1 Introduction and purpose

This document has been drawn up in order to provide an explanation for the performance of the RvA assessment tool 'shadow assessments'. Shadow assessments are used for establishing whether a report (potentially combined with additional audit records) provides a representative picture of the findings made during an audit and whether, on the basis of that, a reliable certification decision can be made.

This is undertaken by an RvA assessor who, together with the Certification Body (CB) auditor, returns to the audit location in order to undertake an on-site verification (in other words in the environment in which the audit was carried out, and using the documentation of the auditee and the available audit records) of the effective undertaking of the audit (by investigating specific audit trails, justification for the random samples taken) as well as the reliability of the available audit records, such as audit notes and the audit report.

Unlike witness audits, this tool is less suitable for monitoring audit skills such as interview techniques, observations, time management, etc.

Important advantages of a shadow assessment are that they have no influence on the undertaking of the audit (after all, the assessment is undertaken subsequently on an audit that has already been conducted) and in theory all audits that have been undertaken can be considered for this.

Shadow assessments can replace some parts of witness audits (or parts of the office assessment); the aim is that these do not cause an increase in the assessment time/costs for a CB. A shadow assessment will in many cases take less time than (full) witnessing. On the other hand, the CB also has to make the auditor available for this, which means that he/she is unavailable for other work at that time.

Nor is it the intention to repeat an audit; the RvA assessor looks at whether aspects of the audit as reported by the auditor can indeed be confirmed on the basis of documents and records of the auditee and the explanation and notes of the auditor.

2 Scope

Shadow assessments are undertaken for schemes within the accreditations for management system certification (ISO/IEC 17021-1), such as QMS (and on QMS-based certifications such as HKZ¹), EMS, VCA²/OHSAS and FSMS certification for example. In addition, shadow assessments are used following notifications and/or in order to conduct a special assessment, in other words with the aim of investigating on site whether a specific aspect

¹ Foundation for the Harmonisation of Quality Assessment in the Health Care Sector

² Contractors Safety Checklist

has been assessed in the proper manner. A shadow assessment can also be used in situations in which few audits are available, for example when expanding the scope of accreditation. An extra condition is therefore that the selected audit has been undertaken in accordance with procedures that have already been assessed, without there being significant changes resulting from non-conformities.

In consultation with the relevant RvA expert it can be decided to use shadow assessments for other accreditations, such as EN ISO 14065 or EN ISO 17065 (for example in schemes where an audit is an important part of the assessment).

3 Explanatory notes regarding the performance of shadow assessments

3.1 Planning

The RvA Process manager accreditations/Senior project assistant (PMA/SPA) determines on the basis of RvA policy how many witness audits have to be undertaken and in what schemes and (clusters of) sectors. Of these, some (at least 1 and maximum 25% per accreditation cycle) are to be undertaken as a shadow assessment (for the time being the RvA regards the conducting of shadow assessments as one of the potential witness audits as required within the framework of IAF MD17). This is recorded in the long-term programme.

In consultation with the RvA team leader (TL), the PMA/SPA appoints one or more Assessors to conduct a shadow assessment. This RvA Assessor then selects (where necessary in consultation with the TL and the PMA/SPA) which of the witness audits can be replaced by shadow assessments. The preference is that he/she does this at the CB's office. The following possibilities are envisaged:

- 1 For regular assessments at CBs, where the witness audits are not separate from the office assessments, the PMA/SPA instructs the RvA assessor to make a selection (see below) during the office assessment of suitable audits for shadowing.
- 2 For CBs, where the witness audits are separate from the office assessment, the PMA/SPA instructs the RvA assessor to make a selection of suitable audits for shadowing. If possible, this can be undertaken during one of the periodic visits or a short, extra planning visit can be scheduled.

The relevant assessor preferably makes an appointment at the office of the CB for the shadow assessment to be undertaken. In consultation, this may be coordinated by the PMA/SPA if there is not an opportunity for this during the office visit.

A shadow assessment is undertaken by an RvA assessor, if necessary (for example for scheme and sector expertise) with the support of a technical expert. The same rules for regular witness audits apply for the deployment of a technical expert.

The RvA assessor selects audits from the dossier random sample on the basis of the following (principle) considerations:

- compliance with the selection criteria as notified by the PMA/SPA (scheme and cluster, see above);
- no audits by auditors recently assessed during witness audits or other shadow assessments, unless stated otherwise by the PMA/SPA;
- the audit was undertaken recently (preferably less than 3 months ago);
- the dossier relating to the selected audit contains no findings which may already give a reason for establishing non-conformities (for example with regard to the use of qualified and competent auditors, planned and/or spent audit time, significant lack of clarity in reporting or suspicion of soft-grading). These aspects can result in non-conformities during the office assessment and normally mean that that audit should not be selected;
- from the aspect of practical feasibility, for the time being the main audits chosen are those that have been conducted by 1 auditor (audits undertaken using multiple standards are permitted). It is possible to deviate from this; in that case, the shadow assessment is, in principle, to be undertaken by the lead auditor.

The RvA assessor makes an appointment in principle with the organisation for the shadow assessment and communicates this with the RvA office. The office will confirm the appointment with the CB. The expected amount of time is approximately a half day on site for undertaking the assessment and a half day for preparation and reporting.

3.2 Preparing for the shadow assessment

As a minimum, the CB must provide the RvA team with the following records from the relevant dossier:

- the audit report, including adopted non-conformity reports;
- the remarks (positive and negative) from any review or decision-making for (re-) certification;
- the previous audit report (if applicable), including outstanding and settled non-conformities;
- the certificate (for a certified client);
- the audit plan for the relevant audit;
- the 3-year audit programme for the relevant client;
- contract assessment information, such as questionnaires, registrations, etc.);
- in the case of a re-assessment audit, the results of the past performance review.

In addition, the CB must also make the procedures relating to the performance of audits and the report available for this assessment.

On the basis of the above the RvA assessor will prepare an assessment plan containing the focus topics. On the basis of these topics the PMA/SPA will, on the recommendation of the RvA assessor, request the CB or the client to make additional documentation available during the shadow assessment (stated in the assessment plan).

The focus topics selected depend on the findings of the CB and the report on these, and shall consist of a balance with more general system topics (such as internal audit, management review or document control), more process-focussed topics (such as operational control or control emergency measures), specific scheme elements (such as risk analysis, significant determination, evaluation of compliance with legislation, customer satisfaction and suchlike) or improvement aspects (such as corrective measures, improvement programmes, etc.).

The CB must prepare its client by:

- stating in its contracts (directly or indirectly, for example via reference to a regulation) that various forms of an RvA assessment are possible for the client. This gives the CB the possibility of specifically stipulating a witness audit or a shadow assessment;
- agreeing the date of the assessment with the client;
- clearly informing the impact this will have on the client (see below);
- requesting a suitable room at the client's premises where the shadow assessment can be undertaken;
- specifically requesting whether the client can arrange the following for an announced CB audit:
 - a brief guided tour (when stated in the RvA assessment plan);
 - availability for inspection of the client's system documents, with the most important records (for example those relating to internal audits, management review, applicable risk analyses and requirements arising from legislation and monitoring evaluations). These do not therefore need to be sent to the RvA;
 - availability of any additional items requested by the RvA assessor (for example specific documentations requested via the assessment plan);
 - a contact person from the CB's client who is available at the start of the audit to give a brief introduction with regard to the client's activities, and who can remain available in the background for clarifications (in principle the RvA assessor restricts himself/herself to questions addressed to the CB auditor).

The CB should prepare its auditor by:

- clearly instructing the auditor about the purpose and the function of a shadow assessment;
- asking the auditor to take with him/her to the shadow assessment the audit report and any additional auditor notes or other records/notes made during the audit so that relevant justifications can be given (especially with regard to the areas indicated by the RvA assessor in the assessment plan);
- providing the auditor with all documents provided subsequent to the audit (such as additional information, or corrective measures).

3.3 On site

The conducting of a shadow assessment consists of the normal aspects of an assessment: an opening interview, a brief guided tour, three to four assessment topics, preparation and a final interview. In principle, the CB's client is only present during the opening interview and the guided tour; for the other aspects the aim is for these to be undertaken by the RvA assessor and the CB's auditor. During the guided tour the RvA assessor can ask for clarifications from the client's representative. During the rest of the shadow assessment the RvA assessor will generally only communicate with the auditor and, in principle, the CB's client will not be involved in the assessment.

After the opening interview the RvA assessor can provide a further explanation with regard to the relevance of the topics that have been selected. The RvA assessor checks with the CB's auditor whether that which is stated in the audit report can be traced back to the documents, records or processes assessed by the auditor. For example, if the auditor has concluded in the report that the client has listed all relevant legislation and the compliance with the legislation has been demonstrably evaluated then the RvA assessor can ask for the records that we used to validate that so the RvA assessor is able to verify whether the auditor's findings can or cannot be reproduced.

If it is not immediately evident from the documents inspected then the auditor can be asked about other items that have been seen/assessed in order to make the findings demonstrable (it is explicitly stated that with regard to this the auditor may make reference to audit notes for example). They must be legible and clearly understandable. However, if it appears that the statements in the audit report cannot be substantiated then this will be discussed with the auditor and the opportunity of providing an explanation will be given. The CB's auditor may also call in the assistance of the client for this in order to help him/her find previously assessed, documented information.

The RvA is aware of the fact that a shadow assessment has limitations, such as:

- the client's documents (certainly procedures) may have changed subsequent to the audit; findings should therefore be based on the documents that were valid at the time of the audit (insofar as possible);
- the client's environment may have changed subsequent to the audit; for example it is only possible to a very limited extent to investigate in detail the observed hygienic situation;
- the auditor may potentially no longer recall all of the lines of reasoning and justifications for the audit trails. Auditor notes and the report should therefore provide an adequately complete picture, though sometimes this may not provide 100% coverage.

These limitations should be taken into consideration by the RvA assessor and should be reported when relevant for the audit or the findings.

3.4 Conclusions and consequences

At the end of the assessment the RvA assessor will take a brief period in order to organise his/her notes, to evaluate the findings and potentially formulate them if they could potentially result in a non-conformity. The RvA assessor will complete form RvA-F150 for this. Feedback will then be provided in an interview with the CB auditor. The CB's representative (the relevant auditor or potentially another representative appointed by the CB) will be asked whether he/she can confirm the factuality of the findings.

Considering the purpose of the shadow assessment then any non-conformity established (by the team leader) will primarily concern the reliability of the report (cl. 9.4.8.2). Other non-conformities can be caused by weaknesses in the area of conducting audits, for example incomplete or non-representative selection of random samples (cl. 9.4.4.1) with regard to the scope/objectives of the audit, inadequate identification of clear gaps in the client's documentations/records (cl. 9.2.2.1.1 or 9.4.6.a), or by soft-grading non-conformities, for example by classing non-conformities as improvement opportunities (cl. 9.4.5.2).

As with a witness audit, no feedback is provided by the RvA assessor to the CB's client. It is up to the CB to subsequently notify the client about the outcomes of the RvA assessment (which can be necessary for example if certain non-conformities are established). The process can of course be explained (the role of a shadow assessment in accreditation). In addition, the client should be formally thanked for its assistance and for making the (meeting) room and documentation available.

Any non-conformity that is found will be confirmed in the normal final interview with the CB and the CB should respond to these in the customary manner in accordance with BR004.

4 Shadow assessment reports

As with the witness audit reports, the shadow assessments reports will be included as detailed reports in the full report.

5 Changes with regard to the previous version

The following significant changes have been made with regard to version 1 dated August 2014:

- amendments to EN ISO/IEC 17021-1:2015;
- more detailed explanation about how shadow assessments are to be used (for example, greater control of selection by the RvA assessor, extended scope of use);
- amendments to reflect changed RvA terminology, i.e. RB → PMA/SPA;
- processing of results from the initial evaluations and feedback from RvA assessors and CBs (for example, clarification of the role of and impact on the CB's client, expectations with regard to the CB's auditor, additions to documents to be provided);
- transition arrangement deleted.