



# Heads Up

Issue: 21

Date: 2003/10/06

To: ANSI-RAB NAP Accredited Certification Bodies and Accreditation Auditors

From: Randy Dougherty, Director of Registrar Accreditation

Re: Improved Planning of Accreditation Office and Witness Audits

The ANSI-RAB NAP is revising how it plans office and witness audits.

Attached is new Guidance for Planning Accreditation Office Audits. This guidance is the outcome of what started out as a project of the QMS Council. The original project was to develop an auditor timetable, similar to that in IAF guidance for certification bodies (CBs). However, with the guidance of the CB representatives on the QMS Council, it was recommended to change to a process-based approach of identifying what needs to be audited, and planning accordingly. The result is the attached guidance. Audit time will be customized for each CB based on its scope of operations and performance.

A related document, to be completed by each CB about 90 days before its scheduled office audit, is Certification Body Matrix of Activity. The information on this document, along with the CB's scope of accreditation, and along with records of previous audits and complaints, will be the basis for the executive audit team leader (EATL) to plan the office audit. (As a side note, the information to be provided by each CB using this form will also contribute to the effective implementation of the new IAF Guidance on Cross-Frontier Accreditation).

Attached are two documents that relate to planning of witness audits. One is a form entitled Witness Audit Criteria. The second is instructions, for use by the EATL, for completing form. The vision I have for this process (of planning witness audits) is that the EATL, with the management of the CB, will agree upon the audits to be witnessed during the upcoming 12 months (that is, the time between the office audits), and will be selected to provide useful information about the effectiveness of the CBs audit management process. Therefore, we will use the results of prior audits, the most recent office audit, and complaints, to identify what may be concerns or weaknesses in the CBs audit management process, and select specific clients or audit teams to witness, for the purpose of determining how robust the CBs audit management process is.

We expect our processes to continually improve, and continually evolve. Therefore, I strongly encourage anyone to call and talk with me directly about any of these initiatives.

## GUIDANCE FOR PLANNING OFFICE AUDITS

All processes listed in both categories include all industry specifics and LOB's the CRB is accredited for.

**Processes that must be included in an office audit:**

½ hour	Opening Meeting
1 hour	Lunch
½ hour	ANSI-RAB NAP Audit Team Preparation for day debrief including the day debrief (including caucusing if more than one auditor on team)
1 ½ - 2 hour	ANSI-RAB NAP Audit Team Preparation for end of audit and any necessary follow-up
½ -1 hour	Closing Meeting
1 hour (including qual.)	Boards, Councils and Committees (e.g. Governing Board, Advisory Board, Registration Committee)
2 hour(not including file time)	Auditor – <ul style="list-style-type: none"><li>• qualification/training process</li><li>• selection process</li><li>• evaluation process (maintaining qualified auditors)</li><li>• auditor file selection for review</li></ul>
1/2 hour	Registration Process (should select a portion of the registration process to focus on during an audit, e.g. re-assessment process)- <ul style="list-style-type: none"><li>• Initial Registration Process</li><li>• Surveillance Process</li><li>• Re-registration Process</li><li>• Registration file selection for review</li></ul>
½ hour	Internal Audit Process for Accredited Main Office including
½ hour	Management Review for Accredited Main Office including
½ - 1 hour per office	Internal Audit Process for extension offices including <ul style="list-style-type: none"><li>• Management Review</li><li>• Affiliates (sampling the offices / affiliates, reviewing all offices over the 4-year accreditation period)</li></ul>
2 ½ hours per standard	Registration File Reviews <ul style="list-style-type: none"><li>• Sample size should be at least 2 files per standard (e.g. ISO 9001, AS9100), 2 international files.</li><li>• An additional 2 files per standard may need to be reviewed based on the outcome of the 2 file reviews in each standard.</li><li>• Plan approximately 1 hour per file.</li></ul>

**GUIDANCE FOR PLANNING OFFICE AUDITS**

- Calculation turns out to be 2 ½ days for all standards ANSI-RAB offers (8 total).

½ hour per standard	<p>Auditor file reviews</p> <ul style="list-style-type: none"> <li>• Sample should begin with the auditors that were used for the reviewed registration files.</li> <li>• Sample size should be at least 4 auditor files per standard.</li> <li>• One auditor may satisfy the sample for several standards, this would reduce the review time.</li> <li>• Additional files per standard may need to be reviewed based on the outcome of the first files reviewed in each standard</li> </ul>
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**Processes that may need to be included in surveillance audits based on data/information provided by the CRB:**

½ - 2 hours	<p>Organization – related bodies including affiliates whom conduct activity on behalf of the accredited CRB  Ownership including organizational structure  Bylaws / Articles of incorporation</p>
½ hour	<p>Marketing / Promotional Material</p> <ul style="list-style-type: none"> <li>• Use of marks (CRB use and certification organization’s use)</li> </ul>
½ hour	<p>Web site</p>
1 hour (including quals)	<p>Qualification/Training of Personnel</p>
2-4 hours	<p>Registration Process for multi-site registrations</p> <ul style="list-style-type: none"> <li>• Including file review (if multi-site registrations is selected the overall file review will be decreased)</li> </ul>
½ - 1 hour	<p>Complaints / Disputes / Appeals</p>
up to 1 hour	<p>Verification of effective implementation of corrective actions for previous NCR’s (including NCR’s generated from complaints) (verification may take place while auditing specific records or processes)</p>
1 hour	<p>AS9100 (due to paperwork)</p>
0 hour	<p>No additional time for all other industry specifics except for the time allocated for files.</p>

## GUIDANCE FOR PLANNING OFFICE AUDITS

### Overall Guidance

- 1) All reviews, audit planning ,etc. needs to be data driven based on the information provided on the pre-audit form.
- 2) Utilize the certificate and schedule to determine amount of audit time (e.g. accredited for all sectors will require additional time, accredited for a majority of the IAF codes will require additional time)
- 3) Option to manage the time spent on files review - For registration file review each surveillance could concentrate on a specific type of file. I.e. One year review surveillances, the next year review re-assessments, next year review initials, another year review multi-sites, another year review transfers.
- 4) All audit planning guidance must be in a public document available to our CRB's. The document should include samples of audit plans – small CRB plan and big CRB plan.
- 5) When a process above is audited the full process including the following should be audited.
  - a) Record maintenance
  - b) Document Control
  - c) Record retention
  - d) Use of the mark
  - e) Conflict of interest issues
  - f) Confidentiality
- 6) All processes above (in both categories) must be included in full system audits.
- 7) Processes in the “May” category may need to be audited depending on the information provided to us by the CRB (e.g. if staff is the same and no new jobs were created or EE's hired we may not need to review how to qualify new personnel)

**Certification / Registration Body's (CRB)**  
**Matrix of Activity**

CRB's Name

Please complete by [due date]. This information will be used by ANSI-RAB in determining the length of the next annual or re-accreditation office audit.

Please include the following attachments with the completed form:

1. Listing of ANSI-RAB Certifications by Country by type of certification including the number of certifications for each country.

**Management System**

**Changes**        Changes including new activity within the accredited management system since the last ANSI-RAB NAP annual or re-accreditation office audit.

Type of change:

- |  |   |
|--|---|
| <input type="checkbox"/> Substantive changes within documented system              | <input type="checkbox"/> Operating System |
| <input type="checkbox"/> Operational Staff   | <input type="checkbox"/> Advisory Board   |
| <input type="checkbox"/> International Activity                                    | <input type="checkbox"/> Ownership        |
| <input type="checkbox"/> Related Bodies  | <input type="checkbox"/> Auditors         |
| <input type="checkbox"/> Other Substantive changes or new activity<br>Explain: ___ |   |

**Complaints**    Number of Complaints CRB has received against the accreditation activity since the last ANSI-RAB NAP annual or re-accreditation office audit

**Auditors**        Number of qualified auditors for all accredited programs  
*Including staff and contract auditors.*

**Staff**            Number of operational staff at the accredited office(s)

**Certification / Registration Body's (CRB)**  
**Matrix of Activity**

**Quantity of registrations / certifications**

**Are files stored electronically?**       Yes       No

**ISO 9001**      Number of ANSI-RAB certifications      \_\_\_       not applicable  
In an attachment - provide the number of ANSI-RAB certifications separated by country.

**ISO 14001**      Number of ANSI-RAB certifications      \_\_\_       not applicable  
In an attachment - provide the number of ANSI-RAB certifications separated by country.

**AS9100**      Number of total certifications      \_\_\_       not applicable  
In an attachment - provide the number of certifications separated by country.

**ISO 13485**      Number of ANSI-RAB certifications      \_\_\_       not applicable  
In an attachment - provide the number of ANSI-RAB certifications separated by country.

**QS-9000**      Number of total certifications      \_\_\_       not applicable  
In an attachment - provide the number of certifications separated by country.

**QS-9000 TE**      Number of total certifications      \_\_\_       not applicable  
In an attachment - provide the number of certifications separated by country.

**TL 9000**      Number of ANSI-RAB certifications      \_\_\_       not applicable  
In an attachment - provide the number of ANSI-RAB certifications separated by country.

**RC 14001**      Number of ANSI-RAB certifications      \_\_\_       not applicable  
In an attachment - provide the number of ANSI-RAB certifications separated by country.

*The following numbers shall include all standards and industry specifics.*

**Multi-site**      Number of ANSI-RAB certifications      \_\_\_       not applicable

**Alternative Method (WDI)**

Number of ANSI-RAB certifications      \_\_\_       not applicable

**Transfers In**      Number of ANSI-RAB certifications      \_\_\_       not applicable

*The following numbers shall include all industry specific certifications since the last ANSI-RAB NAP annual or re-accreditation office audit.*

**New QMS Certs**

Number of ANSI-RAB certifications      \_\_\_       not applicable

**New EMS Certs**

Number of ANSI-RAB certifications      \_\_\_       not applicable

**New Multi-site Certs**

Number of ANSI-RAB certifications      \_\_\_       not applicable

**Certification / Registration Body's (CRB)**

**Matrix of Activity**

**Affiliates (e.g. MOU, MRA) whom conduct activity on behalf of the accredited CRB with regards to the requirements outlined in the applicable ISO Guide and/or IAF Guidance. *If you need more space please contact ANSI-RAB staff for additional forms.***

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Name  
City  
State  
Country

Scope of Activity (including standards)

Number of auditors (contract & full time)

Number of staff (not including auditors)

Frequency of Internal Audits conducted at this affiliate by the accredited CRB

Date of last internal audit

Number of ANSI-RAB certificates issued based on this affiliate's activity

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Name  
City  
State  
Country

Scope of Activity (including standards)

Number of auditors (contract & full time)

Number of staff (not including auditors)

Frequency of Internal Audits conducted at this affiliate by the accredited CRB

Date of last internal audit

Number of ANSI-RAB certificates issued based on this affiliate's activity

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Name  
City  
State  
Country

Scope of Activity (including standards)

Number of auditors (contract & full time)

Number of staff (not including auditors)

Frequency of Internal Audits conducted at this affiliate by the accredited CRB

Date of last internal audit

Number of ANSI-RAB certificates issued based on this affiliate's activity

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**Certification / Registration Body's (CRB)**  
**Matrix of Activity**

**Related bodies (not including affiliates documented above on this form) per the definition in IAF Guidance to ISO Guide 62 section xxx or IAF Guidance to ISO Guide 66 section xxx.**

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Name  
Address

City  
State  
Country

Scope of Activity (e.g. consulting)

CRB's relationship with related body

Please provide RAB a copy of the analysis completed by the CRB per IAF Guidance and ANSI-RAB NAP Advisory 29 Attachment

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Name  
Address

City  
State  
Country

Scope of Activity (e.g. consulting)

CRB's relationship with related body

Please provide RAB a copy of the analysis completed by the CRB per IAF Guidance and ANSI-RAB NAP Advisory 29 Attachment

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Name  
Address

City  
State  
Country

Scope of Activity (e.g. consulting)

CRB's relationship with related body

Please provide RAB a copy of the analysis completed by the CRB per IAF Guidance and ANSI-RAB NAP Advisory 29 Attachment

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**Witness Audit Criteria - DRAFT**

*ANSI-RAB staff to complete*

**CRB:** \_\_\_\_\_

**LOB:**    QMS             EMS

**ANSI-RAB required audit type (check one):**

**Year:** \_\_\_\_\_

Annual

Re-accreditation

QS-9000 Oversight

AS9100 Oversight

RC 14001 Maintenance

QS-9000 TE Supp. Oversight

***Please complete all that apply to determine criteria for this witness audit.***

**Client information**

Client name: \_\_\_\_\_

Location: \_\_\_\_\_

Reason: \_\_\_\_\_

**Auditor Information**

Auditor's name: \_\_\_\_\_

Reason: \_\_\_\_\_

**Location information**

State or Country: \_\_\_\_\_

Reason: \_\_\_\_\_

**Audit type (check one)**

Surveillance

Initial

Re-registration

Follow-up

Multi-site

Stage 1

Stage 2

Reason: \_\_\_\_\_

**Industry Specific (check one) / IAF Scope Category**

TL 9000

Alternative method

ISO 13485

Reason: \_\_\_\_\_

IAF Scope Category:

Reason: \_\_\_\_\_

**If available, what are the next dates for this specific type of audit:** \_\_\_\_\_

*Leave a copy with the CRB.*

## **Instructions for completing the Witness Audit Criteria Form - DRAFT**

### **GENERAL GUIDANCE**

If you do not have specific criteria for a required witness audit do not complete this form. RAB will randomly select audits.

Whatever type of criteria you select for the witness audit you must provide a reason.

When selecting criteria make sure the information makes sense. E.g. if you select QS-9000 witness audit and you provide an auditor's name make sure the auditor is qualified for QS. If you pick a client, an auditor and an IAF Scope Category make sure the client is certified and the auditor is qualified within the scope and make sure the auditor conducts the client's audits.

### **ANSI-RAB REQUIRED AUDIT TYPE (CHECK ONE)**

The required audit type is for upcoming ANSI-RAB required witness audits for the CRB.

ANSI-RAB staff will complete one form per required audit type. ANSI-RAB staff may provide sheets for the next year's required audit types; depending on when the office audit is conducted.

The forms will be included in the office audit binders.

### **CLIENT INFORMATION**

If you are selecting a specific client for ANSI-RAB to witness make sure the client is registered to the required audit type (e.g. AS9100) and make sure you provide the full name and location.

Sample reasons for selecting a specific client:

- A complaint received.
- Information found in a file review.

### **AUDITOR INFORMATION**

If you are selecting a specific auditor make sure they are qualified for the required audit type (e.g. AS9100) and provide the full name.

Sample reasons for selecting a specific auditor:

- A complaint received.
- Auditor contracted from an outside organization.
- Concerns in regards to specific auditor training/qualifications.

### **LOCATION INFORMATION**

If you are selecting a specific location (e.g. Korea) make sure the CRB has clients for the required audit type in the location.

Sample reasons for selecting a specific location:

- Activity being monitored/controlled by a remote office.
- The amount of activity taking place in one country/location.

### **AUDIT TYPE (CHECK ONE)**

If you are selecting a specific audit type make sure it does not contradict the required audit type above (e.g. if the form is for a re-accreditation required audit, do not select surveillance as your audit type).

Sample reasons for selecting an audit type:

- Concerns about the CRB's effectiveness in a type of audit (e.g. EMS Stage 1, multi-site)

## **Instructions for completing the Witness Audit Criteria Form - DRAFT**

### **INDUSTRY SPECIFIC (CHECK ONE) / IAF SCOPE CATEGORY**

If you are selecting an industry specific or IAF Scope Category make sure it does not contradict the required audit type above (e.g. if the form is for a AS9100 required audit, do not select TL 9000).

Sample reasons for selecting an industry specific of IAF Scope Category:

- Amount of activity
- Concerns in an industry specific of IAF Scope

### **IF AVAILABLE, WHAT ARE THE NEXT DATES FOR THIS SPECIFIC TYPE OF AUDIT**

Include audit dates if the criteria above is so specific (e.g. a specific client or alternative method) that the CRB can quickly provide you confirmed or tentative dates.

Tentative may be a specific month or quarter of the year.

If the audit that meets the criteria above has been completed for this year ANSI-RAB will conduct the audit the following year.