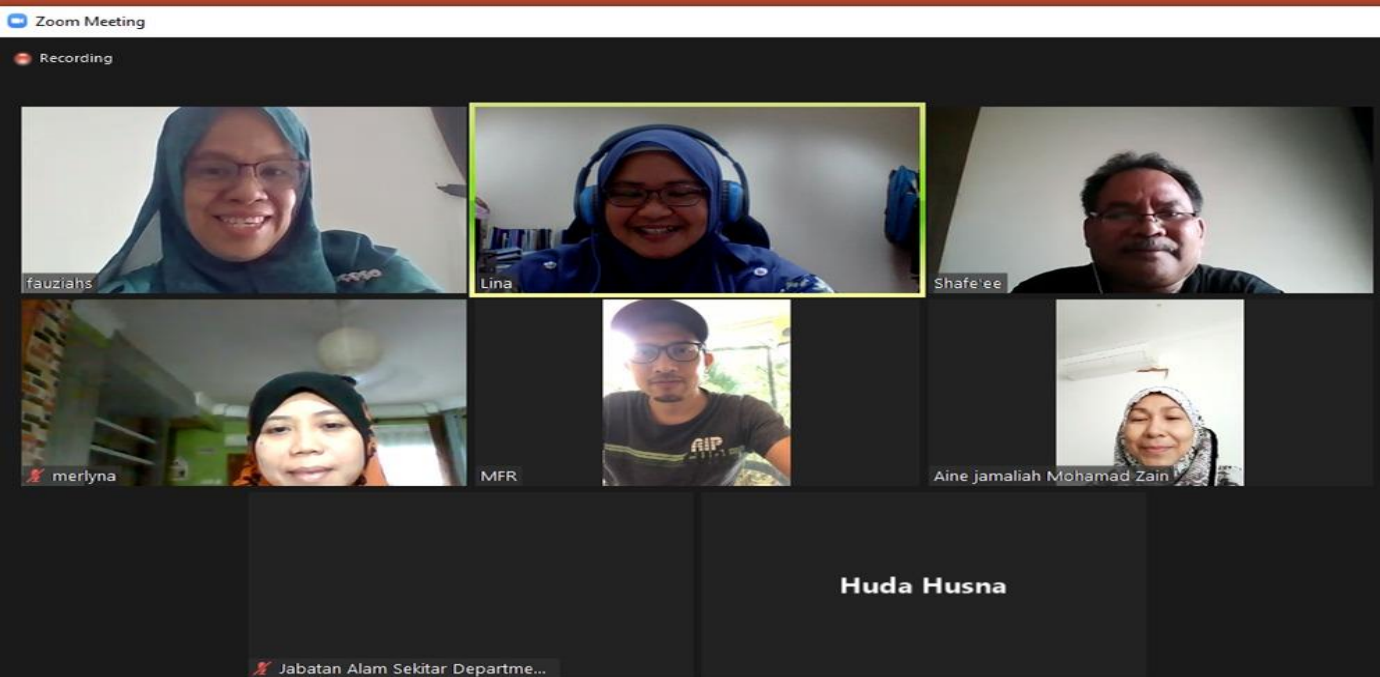# REROUTE YOUR AUDIT REMOTELY - REMEDY FOR SOCIAL DISTANCING

2 SEPTMEBER 2020

SAZLIN BT ALIAS
PRINCIPAL AUDITOR
SERVICES SECTION
MANAGEMENT SYSTEM CERTIFICATION DEPARTMENT

Remote Audit brings us closer and deliver results. Gather vital information, save time, money and engage with your people using the latest technology.

KEEPING UP WITH INTERNATIONAL PRACTICES

Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements　　　ISO/IEC 17021-1

Guidelines for auditing management systems　　　ISO 19011
[Recently Published : Guidance on Remote Audit: 16 April 2020, issued by the ISO Auditing Practices Group pf ISO TC 176](#)
https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html

Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations　　　IAF ID 3

Principles on Remote Assessment　　　IAF ID 12

IAF Mandatory Document for The Use of Information and Communication Technology (ICT) For Auditing/ Assessment Purposes　　　IAF MD 4

WHY THE AUDIT NEED TO BE CONDUCTED

➢ **IAF requirements – A certificate that expires in December 2020 should not be extended.**

➢ **Cost of Remote Audit – Only professional Fees will be charged**

➢ **Rebate 20% for any audits (Remote or Onsite Audit) :
   1st June 2020 till 31 Dec 2020
   *term & condition**

20% of invoice (RM1000-RM10,000)
Invoice more than RM10,000 – rebate only RM2000 per invoice

Message from the **CEO**

Supporting you as we navigate this pandemic together- SIRIM QAS is now offering a 20% rebate on most of its services from 1st June until 31st December 2020.

Dear Valued Customers,

We have been living in uncertain times the past few months as the world, including Malaysia, battles to contain the spread of COVID-19. Needless to say, it is a very challenging time for businesses all around.

With almost 50 years experience in the field of testing, inspection and certification, we have been together with you to overcome numerous challenges over the years. And this time, it's no different. We will continue to be here for you.

As you resume your business operations with the opening up of more economic sectors under the Conditional Movement Control Order (CMCO) which came into effect on 4th May 2020, we are here to support you to ensure continuity to your business.

Mohd Azanuddin Salleh

SIRIM QAS INTERNATIONAL

LIST OF SCHEME AND APPLICABILITY OF REMOTE AUDIT

NO RESTRICTION
(in compliance with ISO/IEC 17021 or ISO/IEC 17065, ISO 19011, IAF MD 4 and IAF MD 5)

ISO 9001 (QMS)	ISO 41001 (FMS)
ISO 14001 (EMS)	ISO 50001 (EnMS)
ISO 45001/ OHSAS 18001/ MS 1722 (OHSMS)	ISO 39001 (RTS)
ISO/IEC 27001 (ISMS)	ISO 21001 (EOMS)
ISO/ IEC 20000-1 (ITSMS)	ISO 18788 (SOMS)
MS 1900 (QMS Shariah)	ISO 18925 (CCC)
ISO 22000 (FSMS)	ISO 29993 (LSP)
ISO 37001 (ABMS)	ISO 22716 (GMPC)
ISO 55001 (AMS)	MS 2610 (MF)
ISO 22301 (BCM)	ISO 17679 (Wellness SPA)

GET THE DETAILS FROM THE SCHEME OWNER

YES WITH RESTRICTION/ EXCLUSION:
➢ RSPO P&C
➢ RSPO SC
➢ CoC
➢ ISO 13485
➢ MSPO SC
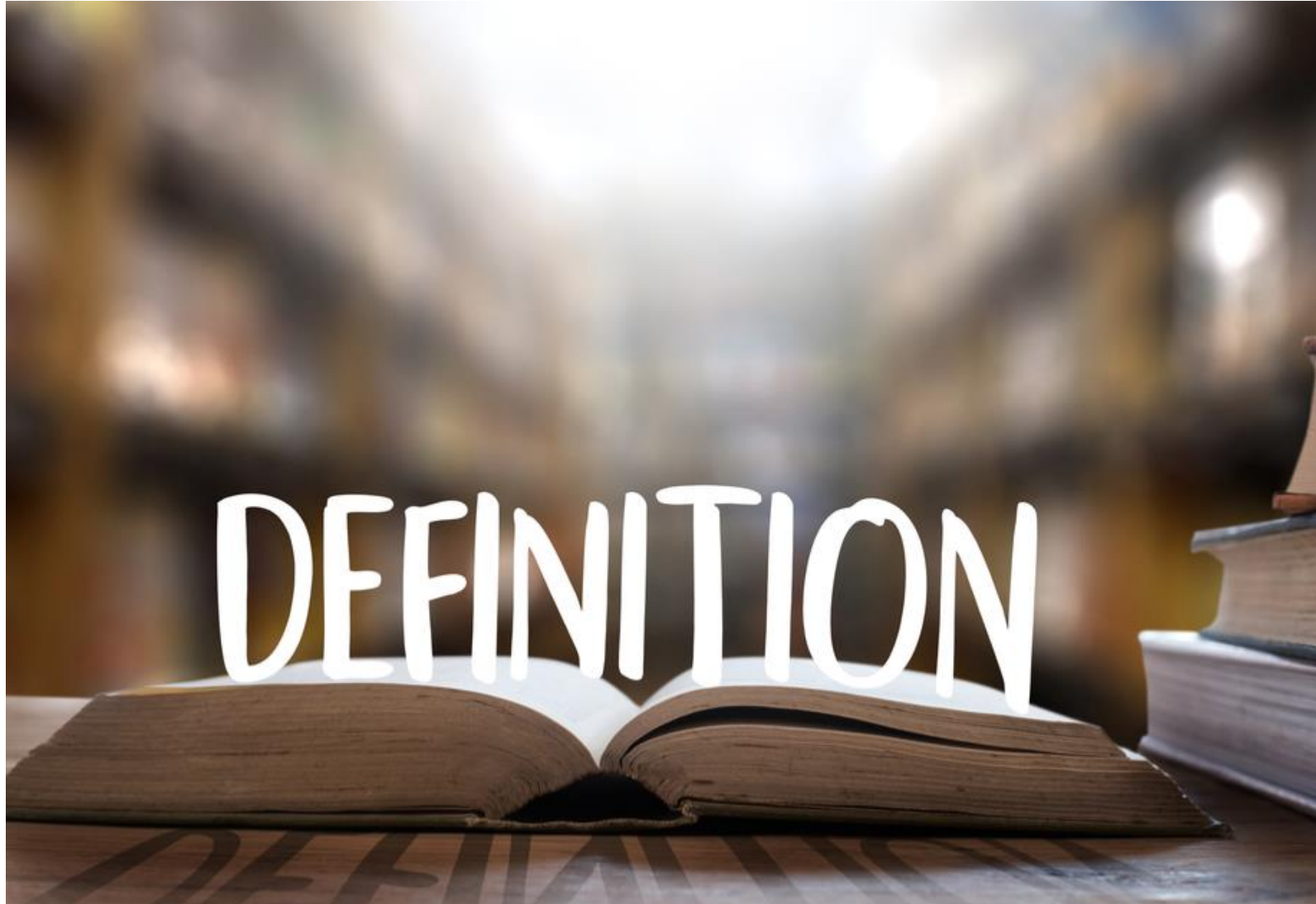➢ GDPMD/ PV/ FA

NO REMOTE AUDIT:
➢ IATF16949
➢ MSPO
➢ MS 1480 (HACCP)
➢ MS1514 (GMP)
➢ ISO 14067 (CFP)

SIRIM QAS INTERNATIONAL

Content

Part 1: Definitions

Part 2: Procedure for Management of extraordinary events

Part 3: Procedure for Remote audit

Part 1

DEFINITIONS

Extraordinary event or circumstances affecting certified organization

"

A circumstance beyond the control of the organization; commonly referred to as "Force Majeure" or "act of God". Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.

Extraordinary events can be classified as:

a) *serious unexpected events e.g. outbreak of pandemic/epidemic, war, country partial or total lock down, etc., which impact both SIRIM QAS International and its clients. This situation may temporarily prevent SIRIM QAS International from carrying out planned audit activities.*

b) *unexpected events which occur only at client' premises or its surrounding areas which may temporarily prevent planned audit activities being conducted at premises.*

Remote audit

> The facilitation of assessment of a client from a location other than that being physically present.
>
> A remote audit can be conducted via web conferencing technology (such as SKYPE, video/ tele conference, etc.) or Information and Communication Technology remotely (such as email, hard copy of documents - together with interview through phone or electronic media, etc.). This is to obtain audit evidence and evaluate it objectively in order to determine the extent of conformity to the audit criteria.

MOST POPULAR CONFERENCE TOOLS

- Skype of Business
- Webex
- Microsoft Teams
- GoToWebinar/GoToTraining/GoToMeeting
- Google Hangout Meet
- 365 Remote Assist
- Zoom

Part 2

MANAGEMENT OF EXTRAORDINARY EVENTS

PURPOSE

This procedure defines the responsibilities and outlining the steps need to be taken in cases where a certified organization is affected by an extraordinary event. This also includes the process of evaluating the current and expected future situation of the certified organization and define alternate potential short-term methods of assessing the organization to verify continuing effectiveness of its management systems.

During Extraordinary Events

Client can choose the following option during extraordinary events :

i) Proceed the audit with other audit methodology without postponement or;

ii) Postponement of the audit within permitted time frame (on-site) or;

iii) Postponement of audit within permitted time frame with other audit methodology or;

iv) Voluntary suspension of certificate

*If clients choose option (i) to (iii), they need to fill up Questionnaire For Extraordinary Events SQAS/MSC/FOR/60-02

Current practice audit methodology

On-site audit is the current practice audit methodology used for all schemes

Other audit methodology

Substitute the on-site audit with remote audit or;

Combination of on-site audit and remote audit

Total audit days shall be the same as the original planned on-site audit days.

Note : Audit day can be increased if additional planning is required.

Certification Activities Managed by Section In Handling Affected Client During Extraordinary Events

Review application from affected client and decide on action.

⬇

Proceed with normal audit process flow.

⬇

Send Summary Of Course Of Actions Taken During Extraordinary Events monthly report SQAS/MSC/FOR/60-03 to Technical Section.

Document & forms

SQAS/MSC/DOC/60-01

GUIDANCE FOR MANAGING CERTIFICATION ACTIVITIES DURING EXTRAORDINARY EVENTS

SQAS/MSC/FOR/60-02

QUESTIONNAIRE FOR EXTRAORDINARY EVENTS

SQAS/MSC/FOR/60-03

SUMMARY OF COURSE OF ACTIONS TAKEN DURING EXTRAORDINARY EVENTS

Page 1

MANAGEMENT SYSTEM CERTIFICATION DEPARTMENT

QUESTIONNAIRE FOR EXTRAORDINARY EVENTS

Name of organization	:
File number	:
Scheme / Standard	:
Scope of certification	:
Type of audit	: Stage 1 / Stage 2 / Surveillance / Recertification / Special
Certificate expiry date	:

Kindly complete the questionnaire and submit to SIRIM QAS International

1)	Type of emergency situation (e.g floods, landslide, temporarily shutdown of some of the production line,etc) which impacts SIRIM audit process.	
2)	Is there a request of postponement from its audit due date? If yes, please state the reason.	
3)	When (date) will the organization be able to function normally (if applicable)?	
4)	When will the organization be able to ship products or perform the service defined within the current scope of certification (if applicable)?	
5)	Will the organization need to use alternative manufacturing and/ or distribution sites (if applicable)? If yes, are these currently covered under the current certification or will they need to be evaluated?	
6)	Is the existing inventory still meets customer specifications or has the customers been informed regarding the possibility of concessions (if applicable)?	
7)	Is there disaster recovery plan or emergency response plan available and it is being implemented and effective (if applicable)?	
8)	Are there any processes and/ or services performed, or products shipped been subcontracted to other organizations? If yes, how are these activities being controlled?	
9)	To what extent the activities of the organization been affected?	
10)	Has an impact assessment been conducted?	
11)	If on-site audit is not feasible, are you agree to allow SIRIM QAS International to carry out remote audit and comply with all the terms & conditions*? If yes, please identify tentative date for the audit.	☐ Agree Tentative date: _____ ☐ Not agree
12)	If remote audit is conducted, a) what are the current electronic media platforms available?	☐ Email & handphone ☐ SKYPE ☐ Microsoft Teams ☐ Other electronic media _____

SQAS/MSC/FOR/60-02
Issue 1 Rev 1

Page 1 of 2

Page 1

Page 2

MANAGEMENT SYSTEM CERTIFICATION DEPARTMENT

QUESTIONNAIRE FOR EXTRAORDINARY EVENTS

b) identify designated personnel to assist SIRIM Auditor throughout the audit	Avaibility of designated personnel <Name and position>: a) _____ b) _____ c) _____ d) _____ e) _____

* Terms & Conditions for Remote Audit:

By accepting the remote audit, I hereby declare, understand and agree with the following terms and conditions;

a) the auditors will be allowed to access to information, documents, records and other evidence deemed essential and necessary.

b) should permission not be granted to access the required information, documents, records and other evidence, SIRIM QAS International may not proceed with the audit.

c) the organization will take all necessary steps to facilitate the remote audit:

i) ensure applicable documents and all the predefined records as stated in the audit plan will be made available;

ii) assign designated personnel to assist SIRIM Auditor throughout the audit (interactive communication such as interview, observing work performed with remote guide);

iii) provide suitable media platforms and suitable office environments whenever possible to avoid interference and background noise;

iv) conduct a trial meeting using the same media platform as agreed upon;

v) taking proper security measures to safeguard and protect confidential information.

Signature	:	_____
Name of authorised representative	:	_____
Designation	:	_____
Date	:	_____

FOR SIRIM QAS INTERNATIONAL USE ONLY:

1) Identify the risks and opportunities that may impact audit effectiveness for each use of ICT under the same conditions, including the selection of the technologies, and how they are managed.

_____

2) Recommendation:

_____

< Name of Group Leader >	< Signature >	< Date >

Decision by Section Head:

☐ Approved ☐ Not approved Reason: _____

< Name >	< Signature >	< Date >

SQAS/MSC/FOR/60-02
Issue 1 Rev 1

Page 2 of 2

Page 2

FORM TO FILL

Questionnaire for Extraordinary Events SQAS/MSC/FOR/60-02

Part 3

PROCEDURE FOR REMOTE AUDIT

PURPOSE

This procedure defines the process how to plan, manage and facilitate remote audits in order to complement traditional oversight techniques, to verify continuing effectiveness of its systems, to establish the level of confidence in the client certification processes by direct observations carried out through an electronic media, supporting and maintaining the integrity of the audit process.

METHODS (remote audit)

**Human interaction (via interactive communication)**
- conducting interviews
- observing work performed with remote guide
- completing checklists and questionnaires
- conducting document review with auditee participation

Non-human interaction
- Conducting document review (e.g. records and data analysis)
- Observing work performed via surveillance means, considering social and statutory and regulatory requirements
- Analysing data

CONDUCTING REMOTE AUDIT
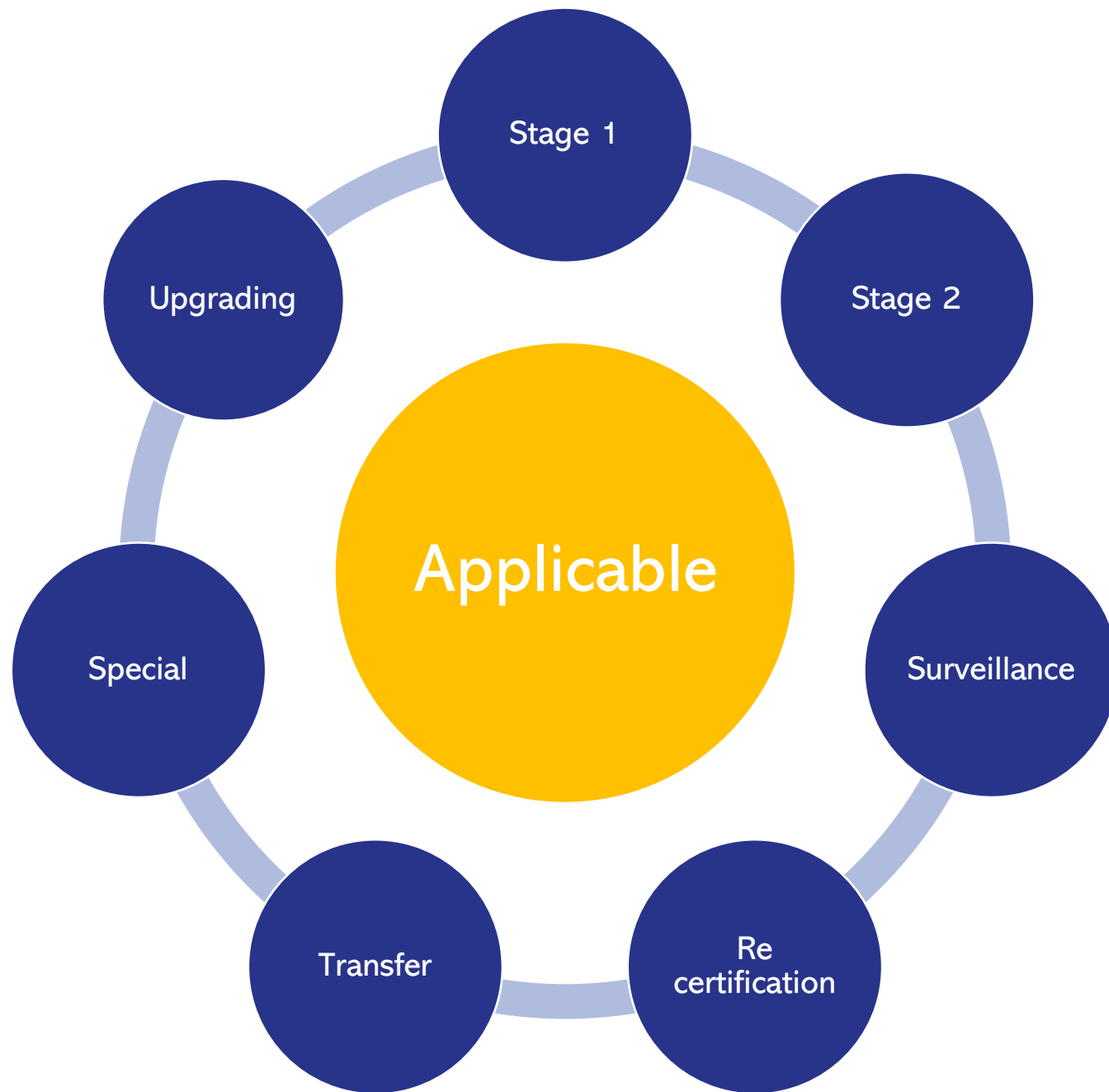
The criteria for initiating a remote audit which may be considered upon mutual agreement with the client and approval by Section Head

Travel to a clients' specific location is not reasonable (i.e., for safety reasons, travel restrictions, etc.)

Unavoidable changes in scheduling for the auditor (personal issues, change in business priorities, etc.)

The number of sites to be audited is difficult for the auditor to completely fulfill within its timeframe

The client has systematic implementation of its management system where records, data, etc. can be reviewed at any site, despite where the work is being performed

Cont..

The criteria for initiating a remote audit which may be considered upon mutual agreement with the client and approval by Section Head

Proven track record of conformance at the location of the remote audit

An activity or activities planned for the on-site audit could not be completed and extending the on-site audit is not the best resolution

The situation requires the audit team to come back for a follow-up audit, but another visit is not easily achievable within a short time frame

Has an auditor (or team of auditors) already familiar with the Management System and its practices and who have visited the client headquarters
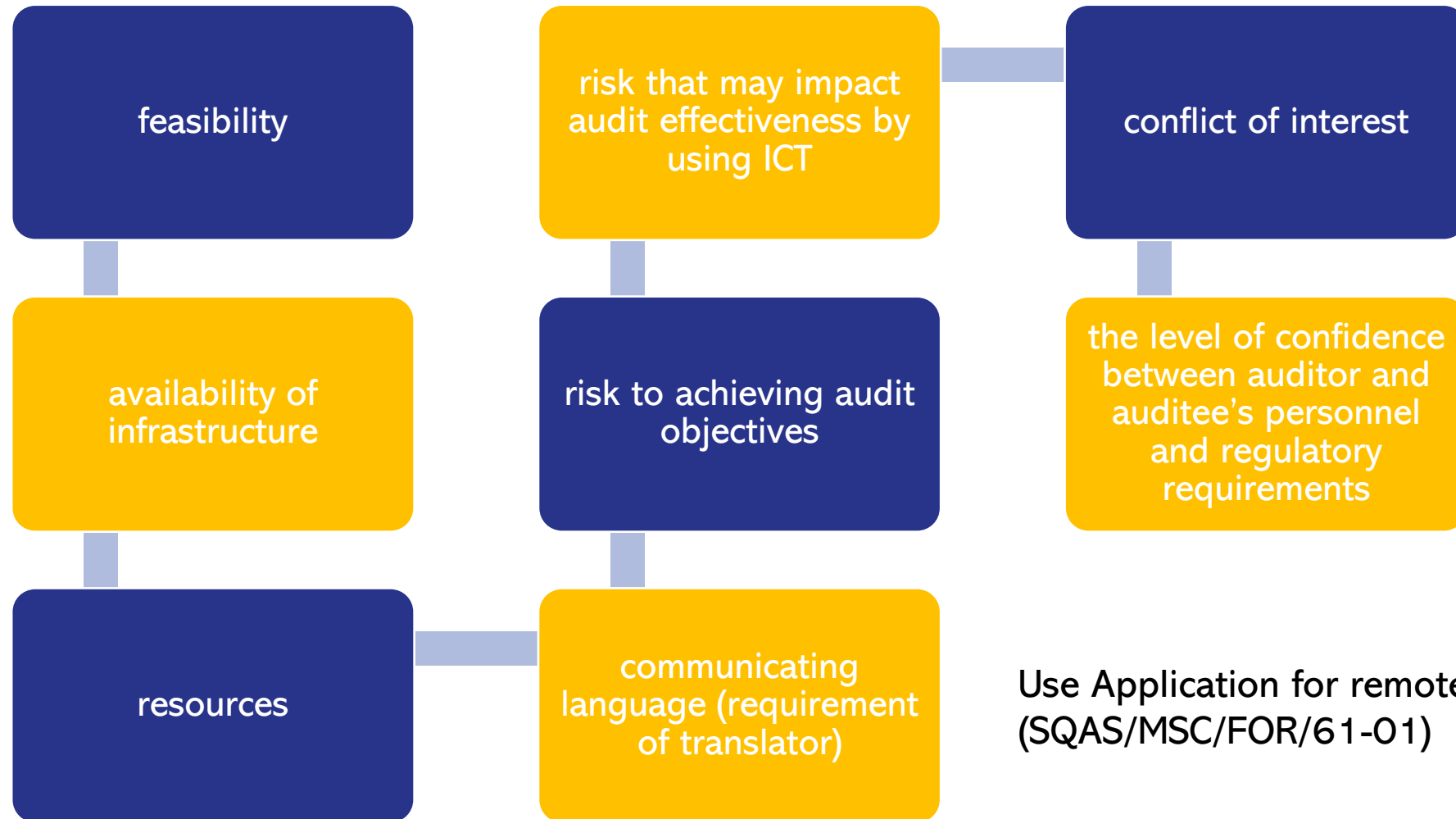
Remote audit is less favourable

When SIRIM has a history of nonconformance at the location being assessed

During initial assessment activity of a new client facility, scope, or significant change

When no on-site audit has taken place for an extended period of time

Determine if remote audit shall be conducted taking into consideration of:

feasibility	risk that may impact audit effectiveness by using ICT	conflict of interest
availability of infrastructure	risk to achieving audit objectives	the level of confidence between auditor and auditee's personnel and regulatory requirements
resources	communicating language (requirement of translator)	

Use Application for remote audit form (SQAS/MSC/FOR/61-01)

In the event that review information cannot be shared remotely (i.e. due to confidentiality, existing corporate policy or access issues), the client has to inform SIRIM QAS International how this will be dealt with (i.e., follow-up, issuance of a nonconformance, etc.).

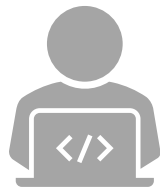# CONFIDENTIALITY

When using ICT for audit purposes, the security and confidentiality of electronic or electronically-transmitted information is important which shall be accordance with information security and data protection measures and regulations.

When using ICT, auditors shall have

competency and ability to understand

utilize the information and communication technologies employed

When using ICT

Only Professional Fess will applicable

> The audit day(s) shall be following the total audit day(s) identified in the application review

↓

> The audit day(s) can be increased if additional planning is required

Application review, audit programme and quotation shall be revised to reflect the changes (if applicable) and shall include a check that the client has the necessary infrastructure to support the use of the ICT proposed.

Facilitation of the audit shall follow

Audit plan

Audit processes

Reviewing audit report

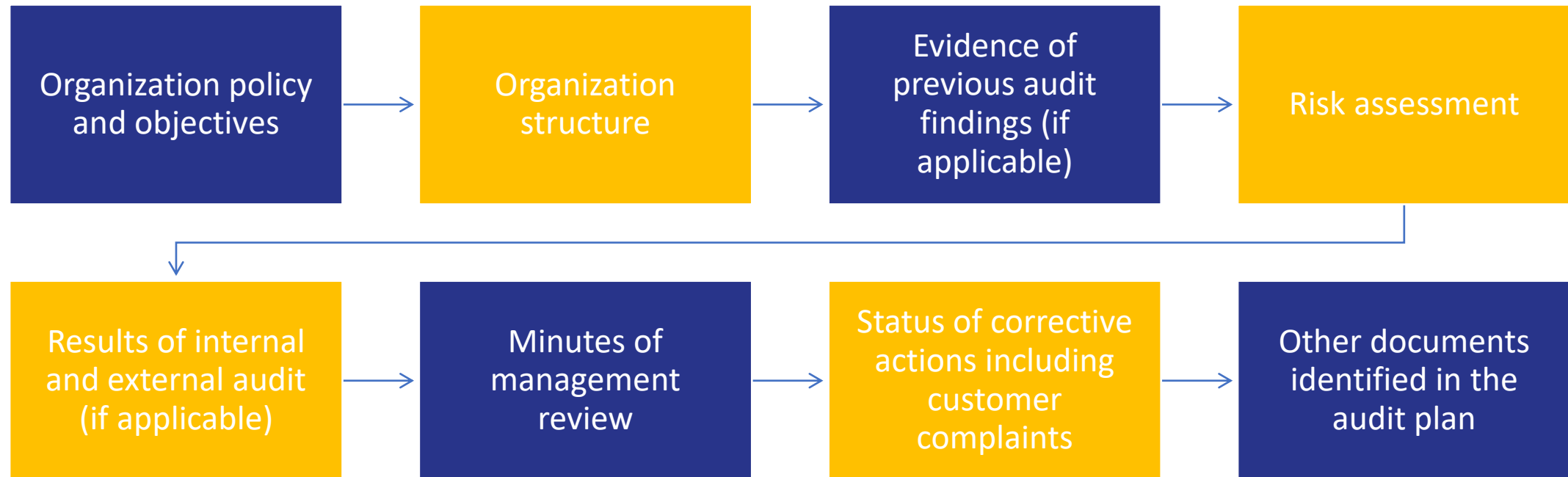Making certification decision

Audit Plan

Prepare audit plan (SQAS/MSC/FOR/61-02) which identified type of documents and records required including the necessary infrastructure to support the use of ICT such as teleconferencing, web conferencing (e.g. Skype, Microsoft Teams, etc.) or email or cloud sharing.

The type of documents needed (prior or during the audit), not limited to:

Organization policy and objectives	→	Organization structure	→	Evidence of previous audit findings (if applicable)	→	Risk assessment

Results of internal and external audit (if applicable)	→	Minutes of management review	→	Status of corrective actions including customer complaints	→	Other documents identified in the audit plan

Identify designated individual(s)

Inform client to identify designated individual(s) that will facilitate, manage and coordinate the arrangements of the audit. This should include translators, when necessary.

Test the platform compatibility

When conducting remote audit, test the platform compatibility between the auditor and client prior to audit including granting security and/ or profile access to the auditor. Both parties shall make their best effort to confirm what was heard, stated and read throughout the audit.

Quiet environment

The audit should be facilitated in quiet environments whenever possible to avoid interference and background noise (i.e., speakerphones).

Safeguard confidentiality

Both parties need to take appropriate measures to safeguard confidentially of data in any format and ensure that proper security measures are taken.

Prepare audit report

Prepare audit reports (refer to specific schemes audit report) which shall conclude audit findings (opportunity for improvements and nonconformity) and recommendation including the extent to which information communication technology (ICT)/ electronic media has been used.

Delete records

At the end of the remote audit, any confidential documents, images, recordings, etc shall be deleted.
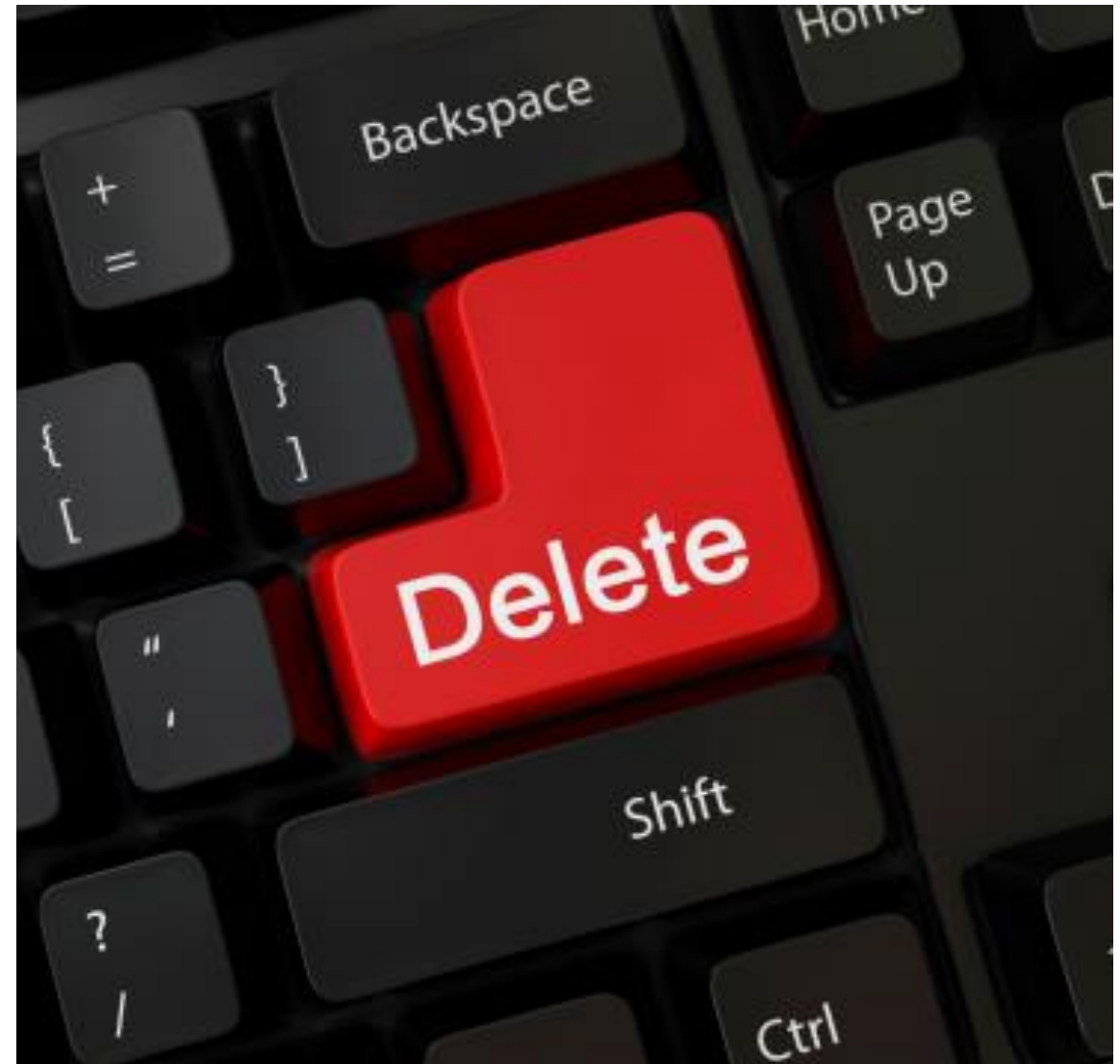
Document & forms

SQAS/MSC/FOR/61-01

APPLICATION FOR REMOTE AUDIT

SQAS/MSC/FOR/61-02

AUDIT PLAN FOR REMOTE AUDIT

TEMPLATE FOR AUDIT PLAN

Page 1

MANAGEMENT SYSTEM CERTIFICATION DEPARTMENT
APPLICATION FOR REMOTE AUDIT

Name of organization	:
File number	:
Scheme/ standard	:
Type of audit	: Stage 1 / Stage 2 / Surveillance / Recertification / Special
Audit method	: ☐ Remote audit ☐ Combination of remote and on-site audit

TO BE FILLED UP BY ORGANIZATION

No.	Details	Comment (Yes or No)
1)	Please identify the reason for applying remote audit or combination of remote and on-site audit:	
	a) Travel to a specific location is not reasonable (i.e., for safety reasons, travel restrictions, etc.).	
	b) Unavoidable changes in scheduling for the auditor (personal issues, change in business priorities, etc.).	
	c) The number of sites to be audited is difficult for the auditor to completely fulfill within its timeframe.	
	d) The client has systematic implementation of its management system where records, data, etc. can be reviewed at any site, despite where the work is being performed.	
	e) Proven track record of conformance at the location of the remote audit.	
	f) An activity or activities planned for the on-site audit could not be completed and extending the on-site audit is not the best resolution.	
	g) The situation requires the audit team to come back for a follow-up audit, but another visit is not easily achievable within a short time frame.	
	h) Has an auditor (or team of auditors) already familiar with the Management System and its practices and who have visited the client headquarters.	

SQAS/MSC/FOR/61-01
Issue 1 Rev 0

Page 1 of 2

Page 2

MANAGEMENT SYSTEM CERTIFICATION DEPARTMENT
APPLICATION FOR REMOTE AUDIT

* Terms & Conditions for Remote Audit:

By accepting the remote audit, I hereby declare, understand and agree with the following terms and conditions;

a) the auditors will be allowed to access to information, documents, records and other evidence deemed essential and necessary.

b) should permission not be granted to access the required information, documents, records and other evidence, SIRIM QAS International may not proceed with the audit.

c) the organization will take all necessary steps to facilitate the remote audit:

   i) ensure applicable documents and all the predefined records as stated in the audit plan will be made available;
   ii) assign designated personnel to assist SIRIM Auditor throughout the audit (interactive communication such as interview, observing work performed with remote guide);
   iii) provide suitable media platforms and suitable office environments whenever possible to avoid interference and background noise;
   iv) conduct a trial meeting using the same media platform as agreed upon;
   v) taking proper security measures to safeguard and protect confidential information.

Signature : _____

Name of authorised representative : _____
Designation : _____
Date : _____

FOR SIRIM QAS INTERNATIONAL USE ONLY:

Justification and recommendation by Group Leader:

_____
_____
_____

| < Name > | < Signature > | < Date > |

Decision by Section Head:

☐ Approved ☐ Not approved Reason: _____

| < Name > | < Signature > | < Date > |

SQAS/MSC/FOR/61-01
Issue 1 Rev 0

Page 2 of 2

Page 1   **Page 2**

FORM TO FILL

Application for Remote Audit
SQAS/MSC/FOR/61-01

FORM TO FILL

Audit Plan for Remote Audit
SQAS/MSC/FOR/61-02

Page 1

File no.   :

Date   :

<Client name & address>

(Attn. :   )

Tel No.   :
Fax No.   :

Dear Sir/ Madam,

<u>**<STANDARD: YYYY> – AUDIT PLAN FOR REMOTE AUDIT**</u>

Please be informed that **STAGE 1 / STAGE 2 / SURVEILLANCE / RECERTIFICATION / SPECIAL / TRANSFER AUDIT** of your organization's **certification scheme** against < standard:yyyy > has been scheduled on < date >.

Enclosed please find the audit plan. Please note that the audit plan serves as a guide and may change as the audit progresses.

Please ensure all documents and records identified in this audit plan shall be submitted prior or during the audit. It is also advisable to test the platform compatibility including granting security and/ or profile access prior to the audit.

Thank you.

Yours sincerely,

(................................)
Audit Team Leader
< Section >
Management System Certification Department
SIRIM QAS International Sdn. Bhd.
H/P No.   :
Tel. No.   : 03-
Fax No.   : 03-
E-mail   :

Page 2

AUDIT PLAN

1. **Type of Audit**

   ☐ Stage 1 Audit   ☐ Stage 2 Audit   ☐ Surveillance Audit

   ☐ Recertification Audit   ☐ Special Audit   ☐ Transfer Audit

2. **Audit objectives**

   ☐ To review certification scheme documented information

   ☐ To verify client readiness to proceed for Stage 2 Audit by gaining a sufficient understanding of the client's certification system and site operations in the context of the standard or other normative document

   ☐ To evaluate the implementation, including effectiveness, of the client's certification system

   ☐ To evaluate the continued compliance of the client's certification system to the requirements of the standard and ability of the certification system to ensure client meets applicable statutory, regulatory and contractual requirements, where applicable

   ☐ To confirm the continued conformity and effectiveness of the certification system as a whole, and its continued relevance and applicability for the scope of certification

   ☐ To evaluate the implementation, including effectiveness, of the client's certification system due to transfer of certification from previous CB

   ☐ To verify adequacy and effectiveness implementation of corrections and corrective actions to close NCR arising from the findings of previous audit

   ☐ Others (please specify):

3. **Date of audit**   :

4. **Site of audit**   :

5. **Scope of certification**:

6. **Audit criteria**

   a)   <Standard:yyyy>
   b)   Client's documentation

Page 3

7. **Audit team & role**

   a) Audit Team Leader   :
   b) Auditor   :
   c) Trainee auditor/ Observer   :
      Technical Expert/ Translator/
      Interpreter etc.
   (If there is any objection to the proposed audit team, the client is required to inform the Audit Team Leader/ Head of Section in writing with reason(s) for the objection)

8. **Methodology of audit**

   a) Remote audit (web conference e.g. SKYPE / Microsoft Teams, etc.)
   b) Review of documentation and records
   c) Observation of processes and activities
   d) Interview with client's personnel responsible for the audited area

9. **Confidentiality requirements**

   The members of the audit team from SIRIM QAS International Sdn. Bhd. undertake not to disclose any confidential information obtained during the audit including information contained in the final report to any third party, without the express approval of the client unless required by law.

10. **Working language**   :   English and Bahasa Melayu

11. **Reporting**

   i) Language   :   English / Bahasa Melayu
   ii) Format   :   Verbal and written
   iii) Expected date of issue :   After closing meeting
   iv) Distribution List   :   Original copy issued to the client and copy maintained in the client file

12. **Facilities and assistance required**:

   i) Guide and designated personnel (who may also be the auditee) to assist SIRIM audit team.
   ii) Email, telephone, handphone and suitable electronic media platform shall be available.
   iii) Ensure the documents and records are available and accessible during audit.
   iv) A quiet environment to avoid interference and background noise.

13. **List of documented information**

   a) Organization policy and objectives;
   b) Organization structure;
   c) Evidence of previous audit findings (if applicable);
   d) Risk assessment;
   e) Results of internal and external audit (if applicable);
   f) Minutes of management review;
   g) Status of corrective actions including customer complaints;
   h) Medical device supply records (for schemes under MDA);
   i) Post-market surveillance and vigilance report (for schemes under MDA);
   j) Others (based on scheme)

Page 3

Page 4

14. **Details of audit plan**   :   As follows

DETAILS OF AUDIT PLAN

DAY 1

Time	Agenda	Responsibility
0900 – 0910 (web conference)	Opening Meeting.	SIRIM's auditors and client's representatives
0910 – 0930 (web conference)	Briefing by client's representative on: a) organization activities and system b) any changes to the system since last audit	Client's representative
0930 – 1300 (off-site review)	Review of documentation (if applicable)	
	Review of actions taken on nonconformities identified during the previous audit (if applicable by respective auditor)	
	Areas to be covered • xxxxx • xxxxx	
1300 - 1400	Lunch Break	
1400 – 1630 (web conference)	Assessment on the implementation of the following requirements: • Site tour at production area and non-production areas. • xxxxxxx	SIRIM's auditors and client's representatives
1630-1700 (web conference)	Preparation of audit report.	SIRIM's auditors and client's representatives
1700-1730 (web conference)	Closing meeting: presentation of findings and recommendation.	SIRIM's auditors and client's representatives

Page 4

FORM TO FILL

Audit Plan for Remote Audit
SQAS/MSC/FOR/61-02

Thank you

SIRIM QAS International Sdn. Bhd
sazlin@sirim.my
www.sirim-qas.com.my
Office : 03-5544 5606
Mobile : 012-4335477

Follow us on **social media**

@SIRIMQASInternational