D.4.2 Progress report on how to move forward accreditations in pandemic crisis

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How to move forward accreditations in pandemic crisis (remote audit plan)

II.   Need for remote audits

### A.   WMDA Accreditation Programme

WMDA has developed its Accreditation Programme as a stepwise progress, beginning first with **WMDA certification/qualification** (depending on the level of activity of the applicant organisation) and followed by **WMDA accreditation**, to help registries achieve compliance with the WMDA Standards.

Certification/Qualification: The applicant must comply with a subset of WMDA Standards designated as "benchmark". Certification is awarded for four (4) years with a mid-cycle surveillance occurring two (2) years after certification/qualification. In this step the assessment is based on a desk evaluation through the WMDA Share platform.

(Re) Accreditation: The applicant must hold WMDA qualification status or be renewing their accreditation status. The registry is required to meet all of the WMDA Standards. Accreditation is awarded for four (4) years and can be renewed. A mid-cycle surveillance occurring at two (2) years. The evaluation process to be (Re) Accredited includes an on-site audit.

Therefore, to comply with the requirements of WMDA Certification Scheme, on-site audits should be performed for those applicant organisations going from qualification to accreditation or renewing their accreditation (see diagram below).

Figure 1 – Qualification-Certification-(Re)Accreditation workflow

Qualification-Certification-(Re)Accreditation Workflow
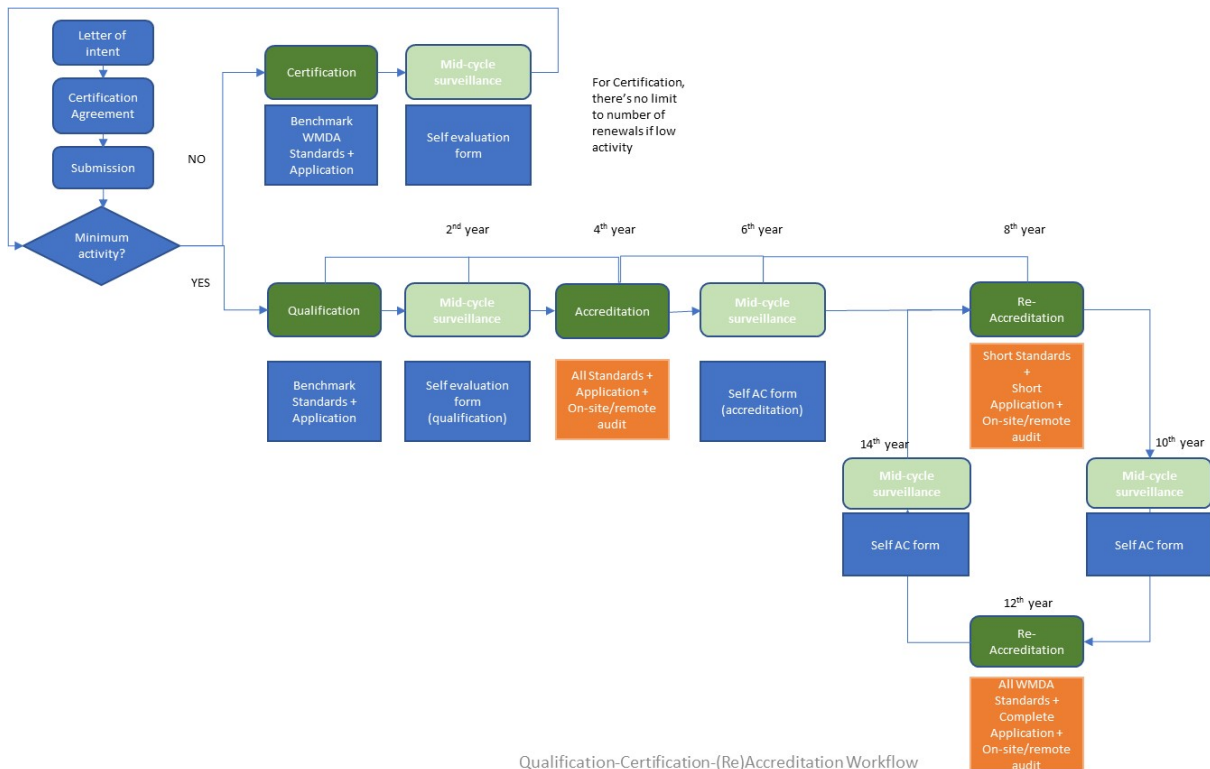
B. COVID-19 Pandemic

WMDA is currently listing 137 different sources of Adult Volunteer Donors and Cord Blood Units from 100 different organizations in 55 different countries. [See: WMDA Total Number of Donors and Cord blood units for up-to-date information].

As of the issue date of this report, 89,55% of the Adult Volunteers Donors and Cord Blood Units come from WMDA Accredited or Qualified organisations.

WMDA Accredited and Qualified organisations are distributed worldwide, the same as WMDA reviewers (auditors). Pandemic travel bans make it impossible to continue with the on-site audits.

Aggravating factors:

- Both applicant organisations and WMDA reviewers work on the health care field.
- WMDA main aims are always to protect both donors and patients.
- Transition to 2020 WMDA Standards: WMDA 2020 Standards version became effective on July 1, 2020. A discontinuation or a big-time gap in the accreditation processes will mean a long delay in the adoption of the new Standards that incorporate important regulations and progress in the field of Hematopoietic Stem Cell transplantation.

That lead to a decision of WMDA Board on April 14th, 2020:

To delay all future applications and put in place alternative options for ongoing reviews.

Part of the impact analysis was focused on gathering information about affected organisations:

Country	UOID	Step	Accreditation Type	WMDA Accreditation	From---to
Ireland	ION-5590	2.Submission	Accreditation (full)	WMDA accredited (D)	ACC to ACC
Italy	ION-7450	2.Submission	Accreditation (full)	WMDA accredited (D/C)	ACC to ACC
New Zealand	ION-8261	2.Submission	Accreditation (full)	WMDA accredited (D)	ACC to ACC
United Kingdom	ION-2731	3.Review and RFI	Accreditation (short)	WMDA accredited (D/C)	ACC to ACC
Israel	ION-5239	3.Review and RFI	Accreditation (full)	WMDA qualified (D/C)	Q to ACC
US	ION-3553	4.RFI response	Accreditation (full)	WMDA accredited (D/C)	ACC to ACC
Israel	ION-4987	4.RFI response	Accreditation (short)	WMDA accredited (D)	ACC to ACC
Finland	ION-9738	4.RFI response	Accreditation (full)	WMDA qualified (D/C)	Q to ACC
Greece	ION-4868	0.Unstarted	Accreditation (full)	WMDA qualified (C)	Q to ACC
Singapore	ION-3785	0.Unstarted	Accreditation (full)	WMDA qualified (D)	Q to ACC
Japan	ION-4364	0.Unstarted	Accreditation (full)	WMDA accredited (D)	ACC to ACC
The Netherlands	ION-8139	0.Unstarted	Accreditation (full)	WMDA accredited (D/C)	ACC to ACC
Czech Republic	ION-4753	0.Unstarted	Accreditation (full)	WMDA qualified (D/C)	Q to ACC
US	ION-1033	0.Unstarted	Accreditation (full)	WMDA accredited (D)	ACC to ACC

WMDA had fourteen organisations impacted from twelve different countries and forty-two auditors involved in these processes from all over the world. An alternative solution for on-site audits was needed so that WMDA was not forced to interrupt the Accreditation Programme.

III. Development, validation, and implementation of Remote Audits
C. Acceptance of remote audits by IAF and RvA.

WMDA Accreditation Programme is preparing its application to *ISO 17065 – Conformity Assessments: Requirements for bodies certifying products, processes, and services.* For that reason, it was crucial to find out the requirements/guidelines from the following entities:

- International Accreditation Forum: IAF ID 3 Informative document for management of extraordinary events or circumstances affecting ABs, CABs and Certified organisations.

- Dutch Accreditation Council: RvA-T051-UK Management of extraordinary events or circumstances affecting RvA accredited bodies and their customers.

Conclusions from the research:

Extraordinary event or circumstance
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.

The Conformity Assessment Bodies (CABs) should assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by an extraordinary event.

The established policy and process of the CAB should define methods for 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.

At that point, it was clear that remote audits were a short-term solution accepted by the Dutch Accreditation Council and that those remote audits should be subject to specific requirements:

- Policies and procedures for remote assessment should include:
    o Criteria for initiating a remote assessment
    o Planning and scheduling of a remote assessment
    o Conducting a remote assessment
    o Post assessment activities.

- There must be agreement with the institution or company on how the assessment will be carried out.

- The assessment must be performed with a secure connection; Microsoft Teams and Skype meet this requirement.

- The assessment plan will consider a less efficient use of time due to possible unfamiliarity with the videoconference service or a faltering connection.

- The assessment report must explicitly state that the assessment has been carried out remotely.

D. Risk analysis

Second step to consider if remote audits were feasible to maintain WMDA Accreditation Programme was to perform a risk assessment. This risk analysis was followed by a mitigation plan to address the identified risks.

The risk assessment methodology includes evaluation of probability and impact as follows:

Impact	Probability		
	High	Medium	Low
High	HH	HM	HL
Medium	MH	MM	ML
Low	LH	LM	LL

LL, LM and ML risks do not need to be addressed in a mitigation plan.

WMDA remote audit risk assessment

PROCESS	RISK	PROBABILITY	IMPACT	NEED TO ADDRESS	COMMENTS/PREVENTION/MITIGATION	ACTION DESCRIPTION
On-line "site visits" (remote audits)	Failure to effectively evaluate status of registry if not physically present to question staff or see documentation	Medium	High	Yes	Can interview staff during remote audit and view documentation on-line. Will require list of documents to be made available in advance and strategy for viewing whether holding up to screen or screen sharing. Will not be as "spontaneous" as requesting while on-site. Can't see daily interactions of staff or observe situations like staff leaving computer unlocked. Will have reviewed documentation (SOPs, forms) in advance.	Create file availability form to determine the files that are going to be inspected during remote audit. During the audit, auditees should show the files via screen sharing.
On-line "site visits" (remote audits)	Unprepared with plan for remote audits	Low	Low	No	Our checklists and overall plan (e.g., opening and closing meetings) guide the audit and can be readily applied to remote audit.	
On-line "site visits" (remote audits)	Inability to evaluate physical infrastructure of registry	Medium	Medium	Yes	Can request tour of registry using camera in cell phone/laptop.	Request presentation or pre-recorded video showing applicant organisations facilities regarding security and information system.
On-line "site visits" (remote audits)	Inadequate information/communication technology	Medium	High	Yes	Difficulties in using the technology for communication like poor internet connections, unfamiliarity with technology, lack of equipment at registry. Need to determine technology to be used in advance in discussion with registry. Need IT recommendation for which technology to use (eg Zoom, Skype, etc). Need advance practice and plan if technology fails during remote audit.	a) Request advise from WMDA Security and Privacy Committee about videoconferencing tools. b) provide to the applicant organisation with tutorials/videos about the use of the videoconferencing tool and offer a trial before remote audit
On-line "site visits" (remote audits)	Potential exposure of confidential information	High	High	Yes	Confidential information can be exposed through poor security of the communication technology. Need security assessment by both WMDA and registry and recommendations.	a) WMDA Security and Privacy Committee to provide Security measures for videoconferencing tools. b) Add specific measures in NDA for reviewers and provide the applicant organisation with the right of request additional measures.
On-line "site visits" (remote audits)	Difficulty in scheduling required time	Medium	High	Yes	Time zone issues may make scheduling difficult especially if plan to allot the same amount of time as on-site. Need to stay on schedule and plan availability of staff accordingly. Need to develop clear plan in advance including documentation to be available in order to remain on schedule.	a) split the audit in several sessions scheduled over 3-4 days. b) replace any auditor that due to time zone issues is unable to participate in the audit c) draft generic audit plan and customize depending on the audit needs.
On-line "site visits" (remote audits)	Inability to determine when remote audit will be sufficient versus need for on-site	Low	High	Yes	Need to develop set of criteria that guide when a remote audit can be utilized and whether a follow-up on-site audit is needed	a) Prepare validation plan for remote audit process b) survey applicant and auditors c) if remote audit is not sufficient determine additional assessments.
On-line "site visits" (remote audits)	Documentation on non-conformities may be inadequate.	Low	Medium	No	Need to report how nonconformaties were observed and to record sufficient information about source.	
On-line "site visits" (remote audits)	Reviewers inexperienced with remote audits	High	High	Yes	Need training program	a) Prepare Webinar about remote audits b) Use WMDA Share to provide information about remote audits to applicants and auditors.

1. Action plan to implement WMDA Remote audits
   a. Alert WMDA membership, survey registries about remote audit
   b. Discuss logistics with WMDA Accreditation Committee and WMDA reviewers (auditors)
   c. Discuss platform security and confidentiality with WMDA's Security and Privacy Committee and other organizations like JACIE, FACT
   d. Develop all supporting documents needed for the remote audit process
   e. Hold pilot audit with registry
   f. Train reviewers
   g. Inform and train registries. Prepare example / instruction videos on 'tour' of registry and 'audit' of one case file
   h. Survey participants in remote audits and assess satisfaction

2. Adjustments after 1st pilot audit
3. Validation

E. Implementation of WMDA Remote audit

a. Survey to registries

A survey was conducted in and the results were analysed by WMDA Accreditation Steering Committee. Please see [Annex I – Survey on Remote Audits]

WMDA received responses from 8 registries already Qualified or Accredited.

Main concerns from registries:

- Preparation of the files to be audited, especially if the registry has paper files.
- Data security and confidentiality.
- Time difference problems.

The results from this survey were incorporated in the risk analysis and all the risks were addressed.

b. Logistics and platform

b.1 Platforms:

As Zoom is the platform used by WMDA for meetings, trainings, and other events, it was decided that WMDA will facilitate remote audits using Zoom, giving the option to the registries to use another platform if they do the necessary arrangements.

- Zoom with registry:

  - WMDA Office will host and ensure security measures (see b.2) are in place; reviewers will be trained to troubleshoot with WMDA Office backup if needed

- Another platform at registry request:

    - Registry will host, ensure security measures are in place, and troubleshoot the platform

    - Recommendations for security requirements will be sent to registry in advance by WMDA

Just as if the review team were on-site, a separate Zoom meeting for reviewers' internal discussions will be organized.

b.2. Security measures

Compliance with regulations in information security is on top of WMDA priorities. One of the most critical items to address in the process of implementation of remote audits was how to perform the audit without compromising registries information.

The Accreditation Steering Committee decided to bring this concern to WMDA Security and Privacy Committee. As a result, the following measures were agreed and documented:

Please see [Annex II – ACC-2705-SP_Security measures for remote audits]

- The communication platform (e.g. Zoom) will be updated by the participants just prior to each audit

- No one may join before the host

- A randomly generated password will be required to participate in the conference

- Only registered participants will be allowed to join the conference; waiting rooms will be utilized

- Once the designated participants are in attendance, the conference will be locked so that others cannot participate

- Reviewers will sign a WMDA confidentiality agreement in advance that will describe the precautions to be taken during the audit

- Reviewers will sign a registry-specific confidentiality agreement in advance if one is provided by the registry

- IT support will be available should problems with the platform arise

- The audit will not be recorded; reviewers will <u>not</u> be allowed to copy any materials e.g. through screen shots

- Reviewers must ensure no one at their location can view screen or listen to audit

- Screen-sharing by the registry will be used to show electronic / scanned files

- File sharing via a secure FTP site with limited access was considered but it is preferable that files should not be available without control by the registry

- Will prevent unauthorized access of registry's database above and beyond files under discussion

b.3 Format

It was an unanimous decision that remote audits will be based on the same principles of the on-site audits and were going to be performed in a similar way but need some additional preparation from both sides, audited organization, auditors and WMDA as Certification Body.

The Accreditation Steering Committee agreed on the following:

- Utilize same checklists as on-line audit but completed electronically

- Review files/documents on-line

- 'Meet' with same staff members, same agenda as on-site

- 'Accompanied' by quality manager / English speaker

- As a substitute of the 'Tour into the registry', a video/slides with focus on key areas like entry to registry, security of IT section can be done.

- Audit will be spread out over several days with appropriate adjustment for time zones

- Add session to remote audit if needed to discuss findings from the desk review (RFI)

- Reviewers will have separate connection to allow confidential discussions during the audit

- Reviewers will need to note details of what they have not adequately reviewed due to remote nature of audit and provide rationale for why this would not result in failure to approve certification.

b.4 Incorporating WMDA 2020 Standards VERSION

WMDA Standards are revised every 4 years to incorporate new/updated regulations and scientific progress on the field.

One of the main worries about the interruption of WMDA accreditation processes in our community was the incorporation of the WMDA 2020 Standards version.

WMDA policy about upgrading Accreditation status to the new version of the standards was to do it during a complete assessment of the organization. That means that organizations should adopt new/changed standards and be evaluated during an Accreditation or Re-accreditation process that takes place every 4 years (see *Figure 1 – Qualification-Certification-(Re)Accreditation workflow).*

For those registries that were in the middle of an (Re)Accreditation process when the pandemic started, the lack of implementation of alternative assessment methods like the remote audits, will mean they will need to wait for 4 years. The same applies for registries that needed to start the process during 2020, since WMDA could not afford to delay these processes and overlap them with the planned processes, due to capacity constraints.

After the remote audit, a specific desk review process to upgrade to 2020 WMDA Standards was created.
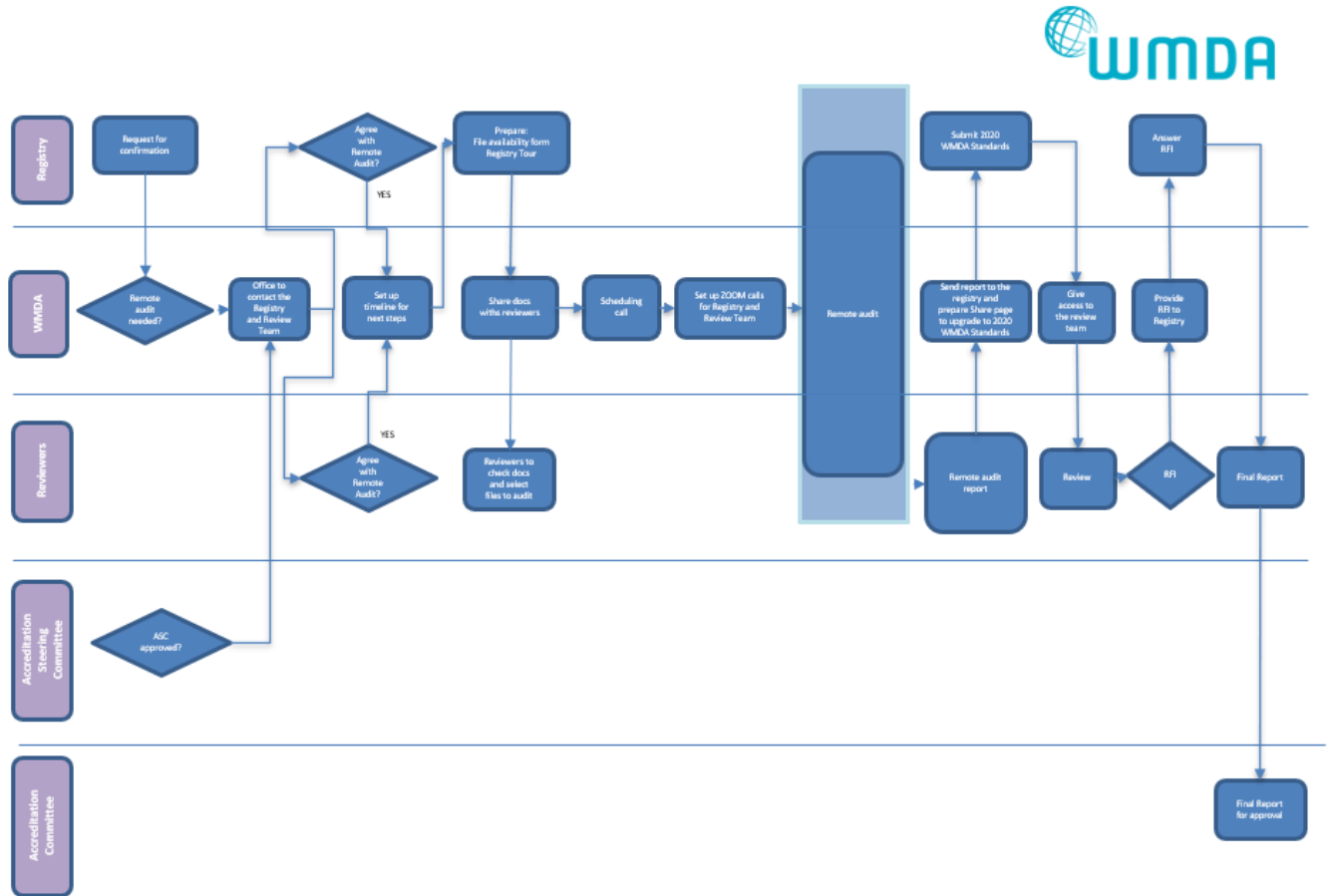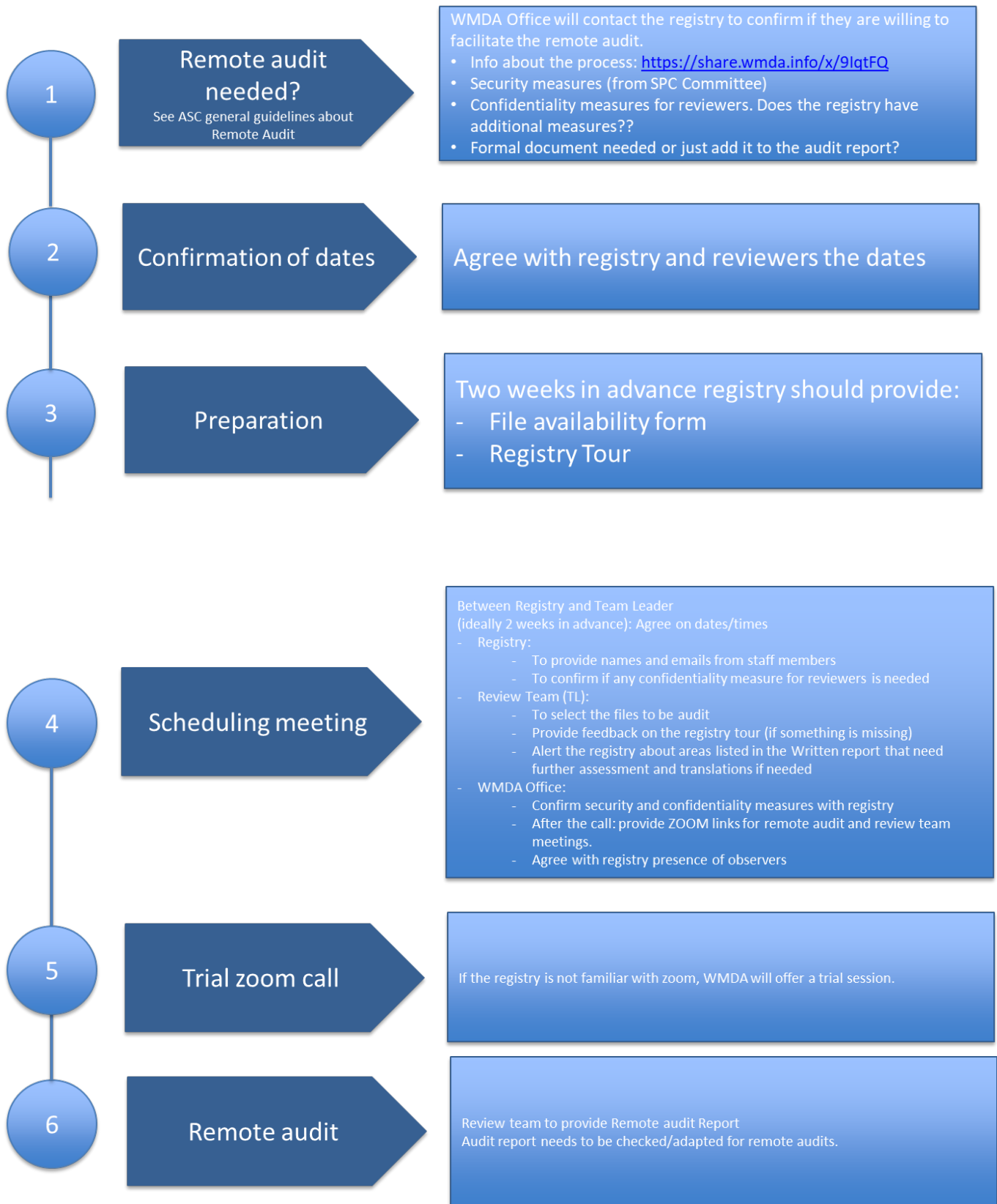
Figure 2 – Remote audit process definition

Figure 3 – Detail of steps and requirements in the remote audit process

1 — Remote audit needed?
See ASC general guidelines about Remote Audit

WMDA Office will contact the registry to confirm if they are willing to facilitate the remote audit.
- Info about the process: https://share.wmda.info/x/9IqtFQ
- Security measures (from SPC Committee)
- Confidentiality measures for reviewers. Does the registry have additional measures??
- Formal document needed or just add it to the audit report?

2 — Confirmation of dates

Agree with registry and reviewers the dates

3 — Preparation

Two weeks in advance registry should provide:
- File availability form
- Registry Tour

4 — Scheduling meeting

Between Registry and Team Leader
(ideally 2 weeks in advance): Agree on dates/times
- Registry:
  - To provide names and emails from staff members
  - To confirm if any confidentiality measure for reviewers is needed
- Review Team (TL):
  - To select the files to be audit
  - Provide feedback on the registry tour (if something is missing)
  - Alert the registry about areas listed in the Written report that need further assessment and translations if needed
- WMDA Office:
  - Confirm security and confidentiality measures with registry
  - After the call: provide ZOOM links for remote audit and review team meetings.
  - Agree with registry presence of observers

5 — Trial zoom call

If the registry is not familiar with zoom, WMDA will offer a trial session.

6 — Remote audit

Review team to provide Remote audit Report
Audit report needs to be checked/adapted for remote audits.

Step 7 — Validation
- From reviewers: where they able to cover the whole areas? Are there any areas that require more assessment? Any risk?
- Registry survey
- From WMDA: Was the process consistent and according to the requirements? Any improvement needed? Any risk?

Step 8 — Upgrade to 2020 Standards
Via evaluation template in WMDA Share

Step 9 — Closure
Final report and certificate.
Do we need to adapt the Final report?

c. Develop all supporting documents needed for the remote audit process.

To implement the remote audits, WMDA has had to develop/adapt supporting documentation that includes:

- WMDA audit checklists: to adapt them to remote assessments

- WMDA Accreditation reports: new reports were created to provide complete information about the new process and to comply with IAF and RvA requirements (see Chapter C: Acceptance of remote audits by IAF and RvA).

- Availability of files for review: WMDA community is built up of a wide variety of organizations with different sizes and resources. Some organizations are almost completely digitalized but others work with paper files. Those who work with paper files will need to scan them to be able to share them during the remote audit.

- Other documents

c.1 WMDA audit checklists

Seven audit checklists are used to guide the audit:

1) Registry
2) Search

3) Donor Verification Typing Requests
4) Workup / Collection
5) Cord Blood
6) Donor Follow-up
7) Quality Management System

All audit checklists were reviewed to assess their feasibility to be completed during the remote audit, to reflect the type of process (remote or on-site audit) and to register the files that have been audited.

Status of the Audit checklists:

- F-ACC-OSA-007 Audit Checklist_Quality Management System v3
- F-ACC-OSA-006 Audit Checklist_Donor Follow-up v2
- F-ACC-OSA-005 Audit Checklist_Work-up Collection v2
- F-ACC-OSA-004 Audit Checklist_Cord Blood v2
- F-ACC-OSA-003 Audit Checklist_Donor Verification Typing v2
- F-ACC-OSA-002 Audit Checklist_Search v2
- F-ACC-OSA-001 Audit Checklist_Registry v2

A Work Instruction was also updated as a guidance to use these checklists, regardless the process is done on-site or remotely.

- WI-ACC-OSA-002 Guidance for Audit checklist v1 20210319

Guidance for Audit Checklist			
Document type	Work Instruction	Approved by	ASC
Document reference	WI-ACC-OSA-002	Approval date	20210319
Version	1	Pages	Page 1 of 4
Pillar	Pillar 4-EQ – Certification Body	Status	Public

Separate instructions just for on-site/remote audits

Guidance for Audit Checklists (On-Site or Remote)

General Instructions for All Checklists

Figure 4 – Example of reviewed audit checklist.

	Onsite Checklist **Search**			
	Document type	Form On site visit Audit checklist	Approved by	ASC
	Document reference	F-ACC-OSA-002	Approval date	20190505YYYYM
	Version	1Draft Version 2	Pages	Page 3 of 3
	Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

No.	Search Report(s) Reviewed Comments				
1	ION and Name of Registry	Click here to enter text.		WACC	Click here to enter text.
7	Are documents correctly completed, dated and signed as appropriate? *WMDA Standard 2.10*	☐Yes ☐No	Click or tap here to enter text.		
	Conclusion			**Comments**	
	Search component is satisfactory	☐Yes ☐No	Click or tap here to enter text.		

Date of audit:Date of site visitaudit:	Registry visitedaudited (ION and WACC):	Type of audit Reviewers: Click here to enter text.	☐ On-siteSignatures: ☐ Remote
Auditors Signatures			

c.2 WMDA Accreditation reports

Before the remote audits were implemented, one unique report was issued at the end of the (Re)Accreditation process, compiling all the information from the desk review and the on-site visit.

WMDA Accreditation is accepted by regulatory bodies in different countries as proof of quality in operations. It is also an accepted global requirement for the exchange of Haematopoietic Stem Cells for patients in need all over the world. For that reason, WMDA stablished three new stages during the pandemic:

- Organisations that did successfully complete the desk review
- Organisations that did successfully complete the desk review + remote audit
- Organisations that successfully completed desk review + remote audit + upgrade to 2020 Standards.

The public information available reflected these statuses and a report was issued for the three stages.

Stage	Report	Remarks
Desk review successfully completed	F-ACC-602-03 Interim (Re)Accreditation report	*Interim (Re) Accreditation Report. Due to the COVID-19 pandemic and according to WMDA Board decision on 14th April 2020, the site assessment of the registry has been postponed. The aim of this report is to provide information about the findings of the desk review until the next steps can be completed. If, as a result of this desk review, the registry is considered compliant with WMDA Standards, the registry will receive an Interim Certificate and will be listed with the status <"Accredited-pending OS 2017"> (for already accredited registry) OR <"Qualification Status + Desk review approved for all 2017 WMDA Standards" (for qualified registry)>.)>.*
Desk review + remote audit successfully completed	F-ACC-602-4 (Re) Accreditation report including remote audit	*Due to COVID-19 pandemic, WMDA has performed a remote audit instead of an on-site visit to assess compliance with WMDA Standards*
Desk review + remote audit + upgrade to 2020 WMDA Standards successfully completed	F-ACC-602-05 (Re) Accreditation report including upgrade to 2020 WMDA Stds.	*Due to COVID-19 pandemic, WMDA has performed a remote audit instead of an on-site visit to assess compliance with WMDA Standards. Evidence of compliance to new and updated WMDA standards implemented July 1, 2020 has been assessed following the remote audit.*

c.3 Selecting files for review

Initial requirements for selecting files agreed by the Accreditation Steering Committee can be found below. The aim of this document is to guarantee that files will be available for the remote audit via screen sharing to remain on the planned schedule:

- In advance, determine what files the registry has in-house and whether there is easy electronic access to files for audit

- Registry will be asked in advance if their files are electronic or paper; will be asked to give range of files available so reviewers can select specific files in advance

- If electronic, registry is notified of the files to make available at the time of the first introductory meeting with reviewers

- If paper, registry will receive earlier advance notice to ensure time to scan files to be shown to the reviewers

- Timing of request for specific files will depend on how much work it will take to prepare files for viewing

The form "F-ACC-Audit documents available" was created following these requirements. This form will allow auditors to select the files in advance and the organization to prepare/scan the files to make them available during the remote audit.

Figure 5 – F-ACC-OSA-008 Audit Documents available

Audit **Documents available**				
Document type	Form-Audit documents available	Approved by	ASC
Document reference	F-ACC-OSA-008	Approval date	20210406
Version	3	Pages	Page 1 of 2
Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

Registry	Click or tap here to enter text.

Please indicate if the files in your organisation are primarily paper ☐ or electronic ☐
The on-site/on-line inspection of the registry will review various files. The files audited will include (1) current files located at the registry and active at the time of inspection and (2) specific files from the past year selected by the reviewers prior to the audit. The reviewers will also request documentation that the registry itself routinely audits off-site files maintained by its affiliated entities (e.g., donor centres).

This form is intended to help the reviewers determine which files are located at the registry and, therefore, available for review during the audit.

Where are the following files located? Put a check in the appropriate box. If registry files are stored off-site in long-term storage, when does that take place?

Files	File Location				Time (Yrs) Before Moved from Registry to Off-Site Long Term Storage
	Registry (on-site)	Donor Centre (off-site)	Collection Centre (off-site)	Cord Blood Bank (off-site)	
Donor recruitment consents					
Searches					
Donor files at stage of CT/verification typing					
Donor files at time of work-up and collection					
Donor follow-up files					
Cord Blood Units					
Informed consent maternal CB donor					
Product specifications of the cord blood unit					
Cord blood files at stage of CT/ verification typing					
Cord blood requested files					

Figure 5 – F-ACC-OSA-008 Audit Documents available (continuation)

Audit **Documents available**			
Document type	Form-Audit documents available	Approved by	ASC
Document reference	F-ACC-OSA-008	Approval date	20210406
Version	3	Pages	Page 2 of 2
Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

For files available on-site at the registry, please provide a list of file identifiers for a recent <u>one year</u> period (does not have to be a calendar year). Reviewers will request 2-3 specific random files to be available for audit during the on-site/on-line inspection prior to the site visit audit.

Files maintained by registry	One year time period covered
Donor recruitment consents	
Searches	
Donor files at stage of CT/verification typing	
Donor files at time of work-up and collection	
Donor follow-up files	
Informed consent maternal CB donor	
Product specifications of the cord blood unit	
Cord blood files at stage of CT/ verification typing	
Cord blood requested files	

c.4 Other documents: COI for auditors

Adaptation of the Conflict-of-Interest, Confidentiality, and document destruction Form.

During remote audits, the same way as in the on-site audits, the auditors might check forms that contain personal information about donors and patients. This information is protected under General Data Protection Regulation (EU) 2016/679 (GDPR).

With the incorporation of the remote audits, new requirements need to be added to the Annex III – F-ACC-401-1 COI, Confidentiality, and document description statement that auditors need to sign before the audit:

- Audit will not be recorded

- Audit materials will not be copied (e.g. through screenshots)

- The location to perform the remote audit will ensure that no one else can view the screen or listen to the audit.

In addition to WMDA form, the audited organizations can request specific requirements regarding confidentiality by communicating to WMDA Office.

d. Hold pilot remote audit

The aim of a pilot audit was to validate the new process and to do any required adjustments identified.

Objectives of the validation process:

- The defined process can be done in a consistent way and complying with all the requirements set.

- Detect if the audit objectives can be covered with the remote audit or if there are any areas that require further assessment.

- Identify any risk not covered in the initial risk assessment.

- Analyse the workload and satisfaction of the audited organization.

The tools used for this validation where:

- Participation of the WMDA Quality and Accreditation coordinator in the pilot audit to supervise the fulfilment of the requirements
- Post-audit surveys to auditors and auditees.

Results of first pilot remote audit

Dates of the pilot remote audit: March 8th to 12th from 9:00 CET to 14:00 CET with 1 hour break.

Review Team: IA (Norway), MK (Czech Republic) and RN (China)

Audited organization: ION-9738 (Finland)

Registry was qualified in 2016. In 2019, the registry applied for WMDA Accreditation, completing the desk review in 2020 and planning the on-site visit when the pandemic started.

Step 1: Remote audit approval	
☒Confirm with the audited organization the willingness to perform a remote audit	*WMDA contacted the auditee and participation on the pilot remote audit was confirmed by email on January 19th.*
☒ Provide information about the remote audit process	*WMDA Office provided detailed information of the:* *- process and* *-all the steps needed* *to complete the pilot remote audit, both in calls and in writing during Feb 18th, 2021.*
☒ Agree on the video conferencing platform and the security measures.	*Security measures determined by WMDA Security and Privacy Committee where shared with the audited organization. Their IT department recommended to use Teams instead of Zoom and arrange all the meetings according to their own security measures. That was communicated to WMDA on March 5th, 2021.*
☒ Determine if the audited organizations require additional confidentiality measures.	*No additional confidentiality measures where required.*

Step 2: Confirmation of dates/times	
☒ Confirmation of dates/times with auditors and auditees.	

Step 3: Preparations	
Auditees should provide at least 2 weeks in advance: ☒ Audit documents available form ☒ Registry tour	*F-ACC-720-04 Audit Documents Available was provided by the audited organization together with slides showing the organization facilities and security systems on February 25th, 2021. No issues were reported regarding the preparation of both documents. Reviewers found documentation appropriate to determine the files to be audited and checked registry security system.*

Step 4: Scheduling meeting	
Audited organization: ☒ To provide names and emails from staff members ☒ To confirm if any confidentiality measure for reviewers is needed	*Stated in WMDA Share*
Audit review Team (Team Leader): ☒ To select the files to be audit ☒ Provide feedback on the registry tour (if something is missing) ☒ Alert the registry about areas listed in the Written report that need further assessment and translations if needed	*Files to be audited were stated in WMDA Share by the Team Leader of the review team. No missing information from registry tour.*
WMDA Office: ☒ Confirm security and confidentiality measures with registry ☐ After the call: provide ZOOM links for remote audit and review team meetings. ☒ Agree with registry presence of observers	*No additional measures where required. As the organization decided to use Microsoft Teams, no ZOOM links where provided. Presence of observers was discussed during the scheduling call and the registry agreed provided that WMDA COI form was signed by observers before the audit.*

Step 5: Trial zoom call	
☐ If the registry is not familiar with zoom, WMDA will offer a trial session	*Not applicable as the videoconference platform used was Microsoft Teams. The audited organization did some internal training.*

Step 6: Remote audit	
☒ Remote audit schedule appropriate ☒ Assessment feasible ☒ Videoconferencing platform	*The pilot remote audit was developed in a smooth way. All audit objectives could be achieved, the proposed schedule fit with the time needed to cover each checklist and no issues with sound or screen sharing occurred.*

Surveys from audited organization and auditors show a high level of satisfaction with the pilot remote audit.

d.2 Adjustments after 1st pilot audit

Even do the process was successful, some adjustments need to be made on the following documents:

- F-ACC-OSA-008 Audit Documents Available

- F-ACC-OSA-007 Checklist Quality Management System

- WI-ACC-OSA-002 Guidance for audit checklist

- WI-ACC-OSA-003 Remote audit schedule

And two more documents were developed to be used as guidance by the auditors:

- WI- ACC-OSA-004 Pre-planning meeting for remote audit

- F-ACC-OSA-009 Checklists Intro-Closing meeting

d.3 2nd and 3rd pilot audits

Two more pilot remote audits were developed to validate the implementation of the process:

- Audited organization ION-3785 (Singapore), on April 12-16, 2021.
- Audited organization ION-2731 (United Kingdom), on June 7-11, 2021

Minor adjustments to the process were made after these remote audits, gathering information through the surveys and according to the observations made by the WMDA Quality and Accreditation Coordinator.

e. Train auditors and auditees

Three main training opportunities are available for WMDA community:

- Information in WMDA Share for audited organizations, explaining the steps to perform a remote audit and giving examples of how auditees can prepare their audit

WMDA

★ Quick access ⌄ | Optimising 'Search, Match & Connect' ⌄ | Supporting Global Development ⌄ | Promoting Donor Care ⌄ | Ensuring Quality ⌄ | Foundation ⌄ | WBMT | Other ⌄ | 📁 office ⌄ | 📌

How to prepare your remote audit

Remote audits are based on the same principles of on-site audits and are performed in similar way but need some additional preparation.

Prepare your files

File availability

The same way they do in the on-site audit, the reviewers will need to see documents associated with each process such as search reports, verification typing requests, donor workup and collection files, follow-up forms, training records, audit forms.

- In advance of the audit, the registry must complete and submit a form indicating the range of files available during the remote audit. Reviewers will select specific files to review in advance of the audit. Registries which do not have electronic files will be given time in advance of the audit to scan the files in preparation for online sharing.
  1. Remember that some staff may be working from home so that access to specific documents may be limited.
  2. Documents may be made available by screen sharing within Zoom communication platform (arranged by WMDA office) or another platform chosen and arranged by the registry, as long as it meets security requirements recommended by the WMDA Security and Privacy Committee.
- Reviewers will be required to ensure confidentiality at their location and may not retain any registry documents shown during the audit.

File availability form

Facilities: security and information system

Registry facilities

One important step during the on-site audit is to check the Registry's facilities.

To cover this point, the registry is required to submit a short video (<5 minutes) or slide set showing the registry facilities in advance of the remote audit.

- The primary focus of the video/slides should be on the security of the registry and its information system showing the security precautions at the entrance to the registry and the limited access to the information system area.
  - Do not breach the registry's security by showing more than is necessary to the reviewers.
- A general overview of the remainder of the registry, including the registry's communication devices should be provided. It is not essential to show all areas of the registry; just give a general impression of the facilities.
  - Do not show any personal health or identifying information during the tour. Be mindful of documents open on desks/workstations and information written on whiteboards.
  - Consider whether personnel may be shown on the video and whether permission to appear in the video is required.

PowerPoint example of virtual tour:

Remote Registry Audit
Virtual Tour
Antarctic Stem Cell Donor Registry

November 2020

📄 Presentation

Making-of "video virtual tour" and tutorial "How to edit your video"

Making-of „video virtual tour"

Presentation

Example: **Virtual Tour Swiss Transfusion SRC**

(click on the image to see the video)

Organising and preparing for the remote audit

Planning the audit

Remote audit schedule

The virtual audit will consist of several sessions scheduled over 3-4 days, at times suitable for reviewers and registry participants. In advance of audit, the review team leader will work with a registry representative to set up the multi-day schedule.

Find here the remote audit schedule

Get familiar with the communication platform

Trial + supporting info

WMDA office will contact the registry in advance of the audit to perform a trial run to acquaint the registry with the use of the platform during the audit.

In addition, you can find some information on Zoom support page

How To Share Your Screen in Zoom

Remote audit

Performing the remote audit

Remote audit

The remote audit will use the same checklists as used in the on-site audit. The registry will be notified in advance as to which documents and files will be audited. Staff to be interviewed will join the session from their desktop and have ability to share documents with the reviewers by screen sharing.

Example: Verification Checklist File Audit

(click on the image to see the video)

- Information in WMDA Share for auditors

Pages / ... / Reviewers - Information 🔒 📎 🕹 Analytics

On-site or remote audit guide

Created by Former WMDA staff member (admin), last modified by Carolyn Hurley on May 29, 2021

Table of contents:

Overview

The audit will occur usually within one-two months after the request for additional information. Two experienced reviewers and possibly a trainee will serve as reviewers. The inspection will focus on an audit of the system proceeding from donor/cord blood search to further confirmatory/verification testing to workup and collection and finishing with donor follow-up. Quality management will also be assessed. A slide set gives an overview of the audit and the role of the audit team leader.

The audit will be organised as described in the Audit Review Plan.

Remote (On-Line) Audits

While the preference of WMDA is to hold on-site audits, it may not be possible in some situations (e.g., during a pandemic or due to local unrest in the region of the registry). When these situations occur, the WMDA Board Committee Accreditation Steering will make a decision to either postpone the on-site audit or perform a remote (on-line) audit. If the registry prefers an on-site inspection, it may request this; however, if the on-site audit cannot be performed within six months, a remote audit will be necessary. WMDA will work with the registry to address their concerns regarding the remote audit.

Remote audits will be conducted during the SARS-CoV-2 pandemic. For the year 2021, the preference of WMDA is to hold remote audits. The Board Committee Accreditation Steering will make a decision to either postpone the on-site audit or perform a remote (on-line) audit based on the situation at the time.

Registries that have received an interim review report

If a registry's application was under review when the SARS-CoV-2 pandemic began and, as a result, the registry has received an interim report, the Board Committee Accreditation Steering has decided that the registry will be audited by a remote audit to avoid further delays in completion of the review process. These registries will also be required to submit evidence of compliance to the current version of the standards prior to conclusion of the review.

Preparation

The registry will provide information as to what files are to be available during the audit. This will vary from registry to registry. For example, a registry may serve as a donor centre and will have files related to donor recruitment on site while other registries may work with independent donor centres and will not have these files on site. In the latter case, the WMDA will evaluate audits that the registry conducts of its donor centres. Reviewers will select specific files to review in advance of the audit. For remote audits, registries which do not have electronic files will be given time in advance of the audit to scan the files in preparation for online sharing.

Deficiencies identified during the review of documentation as well as deficiencies from any prior review/inspection will be further evaluated during the inspection.

A request for more information (RFI) based on a paper review of documents and the audit schedule will be sent to the registry in advance.

Prior to the inspection the reviewers must familiarise themselves with the registry to be audited. This should include at least:

- Review of the document application submitted by the registry.
- Review of written reports from previous audits
- Volume of activity including significant changes
- A review of the follow-up action (if any) arising from previous audits

Prior to the audit, the reviewers will meet to discuss the plan for the audit and identify areas that might require extra attention.

Schedule and Checklists

The audit will be scheduled at a time suitable to the registry and the reviewer participants.

The on-site audit will take place over 1.5 days. Find here the on-site audit schedule template

Checklists are used during the audit. The Guidance for Audit Checklists provides general information for use of the checklist.

A remote (on-line) audit will consist of several sessions scheduled over 3-4 days. In advance of a remote audit, the review team leader will work with a registry representative to set up the multi-day schedule. Find here the remote audit schedule.

The same checklists will be used for on-site and remote (on-line) audits. For a remote audit, the registry will provide a virtual registry tour (video or slide-deck) in advance of the audit. Staff to be interviewed will join the session from their desktop and have ability to share documents with the reviewers by screen sharing. Refer to the Remote Audits-Registry Tour and File Review webinar for additional information.

During the Audit

Reviewers should strive to create a positive atmosphere during the audit. A reviewer should be aware of his/her influence on the decision making process. The reviewer should answer questions but avoid the role of consultant. However, the task of a reviewer is not entirely limited to the disclosure of deficiencies; he/she should connect an observation with educational and motivating elements. Reviewers may disturb the normal work patterns within a registry. Therefore, the reviewers should take care not to put the provision of hematopoietic stem cells at risk, and should carry out their work in a careful and planned way. Reviewers will, while conducting the inspection, have access to confidential information and should handle it with integrity and great care.

An outline of the audit programme

The following outlines the plan for on-site audits. Remote (on-line) audits include the same sessions but are scheduled over 3-4 days as described in the Remote Audit Schedule

Opening meeting–day 1: introductions, plan for audit

The registry will determine who will attend the opening meeting. This might include the head of the registry, the quality manager and staff handling all of the aspects of an international donor search and workup. Reviewers introduce themselves and sign a registry-provided confidentiality document. The reviewers explain the purpose and scope of the audit. There may be some general questions at this time.

The registry presents the management structure of the registry (organisational chart). Staff members are introduced to the reviewers. Usually one member of the registry will accompany the reviewers during the day. This is usually the quality manager of the registry. If the language of the registry is not English, a member of the registry fluent in English should accompany the reviewers. Try to keep to the schedule for the day.

TIP: During the opening meeting , try to make the registry staff feel comfortable and understand the value of the audit.

Rapid registry tour

The purpose of this short tour is to provide an overall assessment of the registry facilities and the general organization of the registry. The details of registry operations should not be covered at this time. The Registry checklist is completed.

Search process

Reviewers will meet with one staff member who handles international search requests. If there are several staff members who handle this stage, the reviewers may randomly select one to interview. This meeting takes place at the workstation of the staff member. The reviewers will ask questions about the search process, will ask to see current files being worked on by the staff member, may ask to see relevant Standard Operating Procedures (SOPs), forms or guidance. Reviewers may solicit information on training. The Search checklist is completed.

- Check the search requests for at least two or three donors/cord blood units received at the moment of inspection OR
- Check the search requests for at least two or three donors/cord blood units received in the last month. Small registries might only have one file available for review and this is acceptable.

Verification typing (confirmatory typing)

Reviewers meet with one staff member who handles international requests. There may be a separate staff member handling requests for cord blood typing. If so, meet separately with this second individual. This meeting takes place at the workstation of the staff member. The reviewers will ask questions about the process, will ask to see current files being worked on by the staff member, may ask to see a relevant SOP, form or guidance. Reviewers may solicit information on training. The Verification Typing and/or Cord Blood Checklists are completed.

- Check at least two or three donor/cord blood unit verification typing requests received and completed for donors/cord blood. Small registries might only have one file available for review and this is acceptable.
- Check at least two or three donor/cord blood unit requests received and not completed. Small registries might only have one file available for review and this is acceptable.
- If no files are available, check the audit report of a donor centre during the quality management review.

Work-up/collection process

Reviewers meet with one staff member who handles the international work-up/collection stage. There may be a separate staff member handling requests for cord blood typing. If so, meet separately with this second individual. This meeting takes place at the workstation of the staff member. The reviewers will ask questions about the process, will ask to see current files being worked on by the staff member, may ask to see a relevant SOP, form or guidance. Reviewers may solicit information on training. The Work-up and Cord Blood Checklists are completed.

- Check HSC donations (at least two or three files) that proceeded to work–up and collection. Small registries might only have one file available for review and this is acceptable.
- Check HSC donations (at least two or three files) that did not proceed to work-up. Small registries might only have one file available for review and this is acceptable.
- Check at least two or three cord blood shipments for international patients Small registries might only have one file available for review and this is acceptable.
- If no files are available, check an audit report of a donor/collection centre covering work-up/collection/cord blood bank during the quality management review.

Quality management, donor follow-up, S(P)EAR, audits of other entities, training

Reviewers meet with the quality manager and any other individuals familiar with the areas being audited. This meeting takes place in a conference room. The reviewers will ask questions about several areas and will request various random documents and files for review. The Follow-up and Quality Management checklists are completed.

The reviewers will ask questions about the process, will ask to see random files, and may ask to see a relevant SOP, form or guidance.

- Donor follow-up, long term and short term
- Adverse events and reactions reporting
- Internal and external audits of associated entities (Collection Centres, Donor Centres, Cord Blood Banks, Transplant Centres, testing laboratories (IDM, blood group, HLA). It is understood that the contents of a specific audit report can remain confidential; however, the reviewers should be able to see the report in a general way and may ask for documentation on follow-up of corrective action.
- Training. Reviewers may ask to see training records of specific staff.
- Quality management. The reviewers will ask questions about the process, may ask to see complaints/corrective actions, and may ask to see a relevant SOP, form or guidance. Versions of documents observed by reviewers during the day are reviewed with the manager to examine whether these versions are the correct ones for the date of the activity.
- Any IT questions may be asked at this time.

Closed meetings

The reviewers will have opportunities to meet privately during the day (e.g., over lunch) to discuss their findings. The evening of day 1 is set aside for the reviewers to continue their discussions and to begin finalizing their report.

Additional questions–day 2

Reviewers pose additional final questions to any of the staff they have talked to during the day and the registry has the opportunity to clarify or correct. Reviewers complete checklists (Summary) and draft the inspection report.

Final group meeting: findings

The reviewers meet with senior registry staff and/or others to verbally share their general observations made during the on-site inspection. Reviewers thank the staff. The deficiencies, observed during the inspection and categorized as described below, must be described clearly. An indication is given verbally of the seriousness of the deficiency. Deficiencies should be reported with reference to the WMDA Standards. A written report is not provided at this time.

Reviewers complete the audit report prior to departure for home.

After the Audit

A written audit report will describe the scope and observations arising from the inspection. The report on the audit should be at least drafted, preferably finalised, before the reviewers depart for home. A WMDA on-site audit checklist is finalized. The report should contain a reference to the WMDA Standards with suggestions to the registry. The conclusions should clearly identify deficiencies, classifying them as critical, major, observation of concern, suggested improvements or comment. Find below the definitions:

Critical issue -Has a high probability of resulting in patient or donor risk, adverse reaction, injury or death. Could result in a product recall. May be a serious violation of WMDA benchmark Standards. Action must be taken immediately (i.e., short but specific timeline) by the Registry to eliminate the cause of these non-compliances. A critical issue will also be raised if a major issue has not been corrected in the agreed time period. A certificate will not be provided until the critical issue has been corrected by the registry. If a critical issue is identified while a certificate is in effect, options include (1) continuation of certification / qualification / accreditation under conditions specified by WMDA (increased surveillance), (2) suspension pending remedial action by the registry or (3) withdrawal of certification / qualification / accreditation.

Major issue - Initial impact may not be associated with immediate donor or patient safety, but these could be affected long term. Has potentially serious implications upon product quality and could lead to "out of specification" situations, or close to failure. Usability of product could be impaired. Another major issue may be the systematic deviation from documented procedures. A major issue will be raised for any action that will require attention prior to the next scheduled surveillance (i.e., biennial self-evaluation or renewal application). The Registry is required to prepare and submit a plan of corrective action within one month of notification and provide specific evidence that they are taking action to address the non-compliance. WMDA will award a certificate if plan of action and objective evidence are acceptable. WMDA will check on progress at six months by obtaining objective evidence of progress. A critical issue will be raised if a major issue has not been corrected in the agreed time period.

Observation of Concern - Cannot be ignored but unlikely to affect donor or patient safety and/or has extremely low probability of product failure. These will be checked with the next scheduled surveillance (i.e., biennial self-evaluation or renewal application), with the expectation that the issue will have been addressed and the registry now fully complies with the Standard. If action has not been taken in the recommended time period, the issue will be raised again but shown as a major issue.

Suggested Improvements – This allows the reviewer the opportunity to highlight any suggestions of improvement identified during the audit. These should be recommendations or best practices the registry is encouraged to consider but is not obligated to implement. The registry should provide comments during the next scheduled surveillance (i.e., biennial self-evaluation or renewal application) as to why they have not implemented the suggestions or if they have implemented an alternate mechanism. Reviewers may continue to repeat previous suggested improvements in their reports; however, if the registry has previously responded that they are not implementing the suggestion, this should also be mentioned in the report.

Comments – Any further information that does not fit into the previous categories.

These deficiencies, improvements and comments are incorporated into the final report.

Completion of Final Report and Decision Regarding Accreditation

The review team will compile their final report, including their observations from review of submitted documentation as well as any from the audit. This report and their recommendations will be forwarded to the Board Committee Accreditation and discussed with the review team during a conference call. During that call, a decision is made by the Board Committee Accreditation regarding approval of accreditation.

- Webinars:

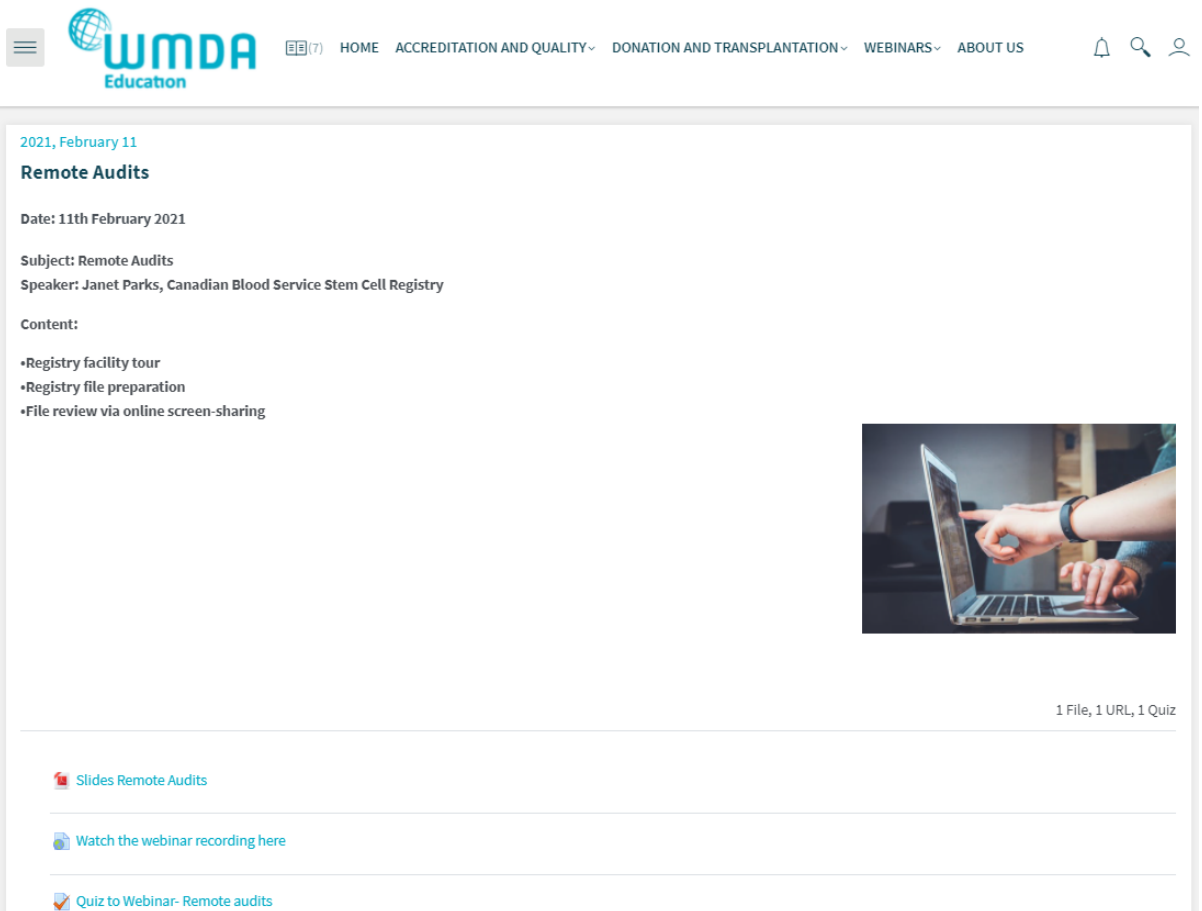WMDA has developed weekly webinars for Ensuring Quality

AQ Webinars | 2021 January - June

Webinars from the WMDA Ensuring Quality Pillar

Lecture weekly on Thursday at 12:00 CET;

Topics:

- 2021, January 14 From RFI Top 10: Application Guidelines: Presenting Organizational Structure and Qualifications of Individuals
- 2021, January 21 From RFI Top 10: Application Guidelines: Interactions with transplant and collection centres, donor safety
- 2021, January 28 What does the Accreditation Steering Committee do?
- 2021, February 4 RFI Top 10: Working with KPIs
- 2021, February 11 Remote Audits
- 2021, February 18 From RFI Top 10: Quality management, SOP's and checking certification of associated entities
- 2021, February 25 Completing an organizational profile in Share
- 2021, June 10 Product code requirement: Changes in WMDA Guidance for standard 8.07
- 2021, June 17 Challenges impacting Backup Donor
- 2021, June 24 Mechanism to ask questions or requests for clarification to the Standards Committee

On February 11th, 2021 the webinar was focused on Remote audits.

≡ **WMDA** Education   📖(7) HOME ACCREDITATION AND QUALITY⌄ DONATION AND TRANSPLANTATION⌄ WEBINARS⌄ ABOUT US   🔔 🔍 👤

2021, February 11

Remote Audits

Date: 11th February 2021

Subject: Remote Audits
Speaker: Janet Parks, Canadian Blood Service Stem Cell Registry

Content:

•Registry facility tour
•Registry file preparation
•File review via online screen-sharing

1 File, 1 URL, 1 Quiz

📕 Slides Remote Audits

📄 Watch the webinar recording here

📝 Quiz to Webinar- Remote audits

The webinar was built in a way that can help auditors and auditees in the preparations of an audit. Slides and recording are made available via WMDA Educational platform and WMDA Share. Auditors need to complete a Quiz to gain continuous education credits.

Pleases see [Annex IV- Slides Webinar]

A second webinar on remote audits was held during WMDA Virtual meeting week 922-26 March 2021).

Ensuring Quality - *slides*

How to address quality management during a pandemic? There will be discussion on remote audits, Key Performance Indicators on Health Availability Check, cryopreservation, listing of cryopreserved products.

- Welcome - Nicoletta Sacchi
- WMDA Standards Committee - Dena Mercer:
- Challenges with compliance to WMDA Standards during the pandemic, and discussion of potential solutions.
- Status of Accreditation in the Time of the Pandemic: Remote Audits and Other Challenges - Carolyn Hurle
- WMDA Quality & Regulation WG - Susie Joron
- Closure

Implementing Remote Audits

- Applications for (re)accreditation required an on-site audit; replacing with remote audit
  - If long delays in scheduling on-site, will perform remote audits for first time accreditation
  - "Short" accreditation applications not currently accepted, must be "full"
- Utilize same checklists as on-site
- Request 5 minute video / powerpoint tour of registry in advance
  - Instructions and examples provided in Share
- Utilize secure on-line platform to interview registry staff and review files via screen sharing
  - Registry may request use of any secure platform (e.g., Zoom, Microsoft Teams)
  - Office will assist with practice session if using Zoom
  - Video example of review of documents via Zoom is provided in Share
- Reviewers may not record or copy screens, must provide secure location to prevent others from accessing the registry's information; may sign additional confidentiality agreement from registry
- Review will take place over several consecutive days using schedule developed by review team leader and registry

WMDA Virtual Meeting Week 2021

Remote Audit Challenges

- Files to be reviewed will be selected by reviewers in advance
  - Registries with primarily paper documentation will need to scan reviewer-selected files in order to provide via screen share
- Large differences in time zones between registry and reviewers will make scheduling difficult
  - Staff working from home or part-time may need to come into office for audit
- Communication challenges
  - Recommend registry perform mock audit in advance to acquaint staff with process
- May require follow-up on-site visit if significant concerns identified

WMDA Virtual Meeting Week 2021

This second webinar included the results of the first pilot remote audit.

First Audit – How Did It Go?

- Registry
  - Satisfied, "everything went nice and smoothly"
  - Preparation about the same as an on-site audit
    - Deciding what to scan, how to show emails, etc. was challenging
  - Comparable to on-site audit in showing compliance
- Reviewers
  - "Surprisingly well, smooth and efficient"
  - Preparation similar to on-site audit
  - Difficult to avoid my registry's work since not traveling

WMDA Virtual Meeting Week 2021

And information regarding the update to WMDA 2020 Standards:

Moving Toward 2020 Standards for Applications Submitted With 2017 Standards

- Qualification will be based on 2017; will update to 2020 when renewing qualification or applying for accreditation
- Applies only to registries with accreditation applications under review at start of pandemic
- Accreditation will be based on 2017 following remote audit
  - Registries must submit compliance with 2020 Standards within 6 months of remote audit
  - Satisfactory desk review (at "on-track" level of review) will update their certificate to 2020 Standards

WMDA Virtual Meeting Week 2021

IV.   Workflow for remote audits and future plans

The workflow for remote audits has been stablished and is now part of WMDA policies and procedures to perform the assessment of applicant organizations to WMDA Accreditation Programme.

Organizations with remote audit in 2021

Applicant organization	Availability form + Registry tour due date	Call with TL	Remote Audit	Post-audit review	Update to WMDA 2020 Standards
FSCR	Due date Feb 22nd. Received	March 1st	March 8-12, 2021	Done	Done
BMDP	Due date March 25th. Received	March 30th	April 12-16, 2021	Done	Done
NMDP	Due date May 25th. Received	2021-06-01	June 14-18, 2021	Done	In progress: auditor confirmed
NHS (Bristol)	Due date May 21st. Received	2021-05-24.	June 7-11, 2021	Done	In progress: auditor confirmed
Ezer Mizion	Early July	TBD (week July 12th)	August 2-6, 2021	Done	In progress: auditor confirmed
IBMDR	Due date Nov 1st. Received	2021-10-02	Nov 18-24, 2021		N.A.
IUBMR	Due date Nov 15th. Received	2021-10-18	Nov 29 – Dec 3		N.A.
NZBMDR	Due date Nov 29th.	TBD	Dec 13 - 17		N.A.

IAF, ILAC and ISO have conducted a survey on remote techniques. More than 4000 participants showed a highly positive view of this technique. The complete survey report can be found here: Use of Remote Techniques Supported by Joint Survey - IAF

WMDA has conducted 6 remote audits this year with very satisfactory results. As part of our commitment to continuous improvement, we will keep on incorporating input from our members and relevant organisations in the accreditation field to improve WMDA audits in the future.

Given the current situation and the specific characteristics of WMDA Community and Accreditation Programme, involving organizations and auditor from all over the world, it has been decided to continue performing remote audits until July 1, 2022. A re-evaluation of the progress to a "new normal" will start on April 2022.

Remote audits
Survey

About the surveys

The aim of this survey is to explore WMDA members openness to remote audits.

PARTICIPATION

As of the date of this report, WMDA has received 8 responses. However, there are 2 responses from the same registry.

Response ID	Registry
2	BBMR
3	NZBMDR
4	The bone marrow donor programme
5	The Bone Marrow Donor Programme
6	Bone marrow donor programme Singapore
7	Norwegian Bone Marrow Donor Registry
8	ZKRD
9	Danish Stem Cell Donors West

CURRENT STATUS OF THE ORGANISATION

Value		Percent	Responses
Already WMDA qualified or WMDA accredited		100.0%	8
			Totals: 8

OPINION ABOUT USING A REMOT AUDIT INSTEAD OF AN ON-SITE AUDIT FOR SPECIFIC DEFINED SITUATIONS

ResponseID	Response
2	I think this is a bad idea, primarily because the document review is already a 'remote audit'. Better to defer onsite visits than attempt remotely. Assessors cannot delve or maintain flexility via the forum of video conferences
3	No concern except for time difference between auditors and registry
4	Onsite audit is easier to ask question and get response on time
5	It will be a good idea to explore but to provide
6	Technology has made it easy for interviews and viewing of documentation. However on-site audits gives the reviewers a better look at the operations in real time and gives the flexibility to ask for reference documents on the spot.
7	I think it might be difficult for reviewers to get an overview on how the registry is operating. Also there might be Challenges with protection of personal information when looking at files etc.
8	From the perspective of a registry it may be an alternative in exceptional cases, but the registry and the WMDA would need suitable and secure electronic systems. Also, our registry has electronic files, for those with paper files it will be more difficult to retrieve and provide documents online, which should contain cases selected randomly. As a reviewer I don't think it is as easy to follow processes and programs you are not familiar with if you only see someone's monitor in a video stream. We commonly point directly to information on screens or in documents when talking to the colleagues, which is difficult if everything is online. There is also no possibility of watching reactions of audit participants.
9	that would be possible.

RECOMMENDATIONS ON THE VIDEO CONFERENCE PLATFORM(S) TO BE USED

ResponseID	Response
2	None - please do not attemp this pilot
3	No
4	Zoom
6	No
7	The only platform I can access from work is Skype.
8	The prioritized aim must be to keep confidentiality while using video conference software for an online audit, we therefore would define the following basic criteria - data transmission must be realized via end-to-end encryption - if software from a cloud provider is used, we need an individual contract for order processing - meeting access may only be possible for invited participants; relevant safety measurements must be installed, e.g. an access code for joining - the meeting may not be recorded by the cloud provider - we would prefer a cloud provider for web meetings with servers located in the EU
9	See also question 5. Due to security reasons, we cannot use all available platforms, e.g. we are not allowed to use Zoom and cannot download the program to install

CONCERNS ABOUT THE SECURITY OF THE INFORMATION

ResponseID	Response
2	Yes
3	No
4	yes
5	There is no concerns in terms of security.
6	No, our video conferencing is done in virtual desktop infrastructure that is secured.
7	There might be challenges with protection of personal information when looking at files
8	Yes, see above. The reviewers participating in an audit would need to be in a room where no other persons could see the information or listen to the conversation.
9	We need to use our official video conference platform if we need to share information.

SITUATIONS IN WHICH A REMOTE AUDIT CAN NOT BE DONE

Value		Percent	Responses
WMDA qualified registry applying for accreditation		75.0%	6
WMDA accredited registry applying for re-accreditation		12.5%	1
The next on-site audit after a major or critical issue has occurred		50.0%	4
Other - please describe (click to view)		25.0%	2

Other – please describe	Count
A remote audit should "only" be done if a registry is applying for reaccreditation "and" the last audit was regular (on site) without major critical issues.	1
Never going to be a fair assessment	1
Totals	2

INTEREST IN PARTICIPATING IN A PILOT REMOT AUDIT

Value		Percent	Responses
No, not interested		62.5%	5
Yes, interested in participating in a pilot, please contact: (click to view)		37.5%	3
			Totals: 8

OTHER SUGESTIONS OR COMMENTS

ResponseID	Response
2	What are we trying to acheive with this? I assume to stick to timetables? This will create an unequal process where one registry could experience a light touch teleconference remote audit yet another a proper assessment that can only be acheived by going onsite
5	Coordination and submission of supporting records will be tough.
6	WMDA should guide registries on examples of what documents to submit according to the checklist.
9	It also depends on the material given to the inspectors in advance and the quality and details of the report from the last accreditation/qualification

Annex II – ACC-2705-SP_Security measures for remote audits

WMDA Security requirements for Remote Audits			
Document type	Specification	Approved by	ASC
Document reference	ACC-7205-SP-Security specification	Approval date	20210209
Version	0.0	Pages	Page 1 of 1
Pillar	Pillar 4-EQ – Certification Body	Status	Public

COMMUNICATION PLATFORM FOR REMOTE AUDITS

- The platform offered by WMDA is Zoom

  - WMDA Office will host and ensure security measures are in place; reviewers will be trained to troubleshoot with Office backup if needed

- The registry may choose another platform providing that:

  - Registry will host, ensure security measures are in place, and troubleshoot platform

  - Security requirements are followed.

SECURITY REQUIREMENTS:

- The communication platform (eg Zoom) will be updated by the participants just prior to each audit

- No one may join before the host

- A randomly generated password will be required to participate in the conference

- Only registered participants will be allowed to join the conference; waiting rooms will be utilized

- Once the designated participants are in attendance, the conference will be locked so that others cannot participate

- Reviewers will sign a WMDA confidentiality agreement in advance that will describe the precautions to be taken during the audit

- Reviewers will sign a registry-specific confidentiality agreement in advance if one is provided by the registry

- IT support will be available should problems with the platform arise

- The audit will not be recorded; reviewers will <u>not</u> be allowed to copy any materials eg through screen shots

- Reviewers must ensure no one at their location can view screen or listen to audit

- Screen-sharing by the registry will be used to show electronic / scanned files

Annex III – F-ACC-401-1 COI, Confidentiality, and document description statement

Conflict of Interest, Confidentiality, and Documentation Destruction Statement			
Document type	Form-COI reviwers	Approved by	ASC
Document reference	F-ACC-401-1	Approval date	20210304
Version	2	Pages	Page 1 of 1
Pillar	Pillar 4-EQ – Certification Body	Status	Confidential

CONFLICT OF INTEREST, CONFIDENTIALITY, AND DOCUMENT DESTRUCTION STATEMENT

Organisation to be reviewed: _____

Reviewer: _____

Please return by email (accreditation@wmda.info) to the WMDA office before performing the review.

1. Conflict of interest

☐ I do <u>not</u> have a conflict of interest regarding the review of the above-named organisation. A conflict of interest is defined as any interest in an application that is likely to bias my review of it. Examples of conflicts of interest include employment of myself or any family member by the organisation or affiliated organisations under review, a direct financial benefit to me from the organisation under review related to the application, a consultant relationship (paid or unpaid) with the organisation under review, or the presence of a long-standing disagreement between myself and the organisation under review. I agree that my review will be impartial and objective.

☐ I <u>have</u> a conflict of interest and describe my conflict of interest as the following:

2. Confidentiality

I agree that all information obtained or created for this review will remain confidential. I will not discuss it with anyone except the review team and any other WMDA entities involved in the review (e.g., WMDA Accreditation Committee, WMDA office, WMDA Board). I will ensure the secure handling of confidential information in my possession pertaining to the ongoing review.

If a remote audit takes place, I agree that the audit will not be recorded, audit materials will not be copied (e.g., through screen shots) and the location I will use ensures that no one else can view my screen or listen to the audit.

3. Document destruction

I understand that material from the organisation under review cannot be used for any purpose other than the review itself. I agree to destroy or delete all registry application materials, electronic and hardcopy, that I may possess as soon as the WMDA office has informed me that the review is completed.

Signed and date: _____

Remote Audit--Registry Tour and File Review

matching donors • serving patients

- Reviewers obtain continuing education credit by taking short quiz on this webinar through WMDA education platform

February 11, 2021
Janet Parks, ASC

Overview

These slides provide information about the following aspects of a remote audit :

- Registry facility tour
- Registry file preparation
- File review via online screen-sharing

Registry Facility Tour

- The registry should provide a virtual tour of the registry facilities in advance of the audit, to cover elements in the 'Registry Checklist':
  - Short (<5 minutes) video or slide set
  - Focus on security (e.g., registry entrance, information system area access precautions, communication devices)
    - Do not breach security by showing more than is necessary
  - Provide general overview/layout of registry
    - Do not show any personal information in the video
    - Ask permission of personnel to be shown in the video

5

Registry Tour Example-Video

6

Registry Tour Example-Slides

Location / Address

The Antarctic SCD Registry is located at 11333 Bering Street, South Pole, Antarctica.

The registry occupies all of the top (3rd) floor of this building (## square feet).

The building is open during usual working hours and is locked overnight and on weekends. Access to the third floor by elevator or stairs is also locked outside of work hours.

Full example slide deck is available on the WMDA share

Access to Registry

Arriving in the elevator, visitors must be admitted by a receptionist who sits behind a locked door.
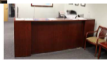
Visitors are logged in, must wear a visitor pass, and must be accompanied at all times by a staff member.
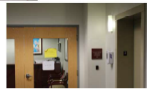
Deliveries are accepted by the receptionist.

File Preparation

In advance of the audit:

- Registry will submit a form with the range of files to be available during the remote audit
  - If files are primarily electronic, registry will be informed which files will be reviewed at the introductory audit meeting
  - If files are primarily paper, registry will be given sufficient lead time before the audit to scan selected files for online viewing

8

Registry Preparation Tips

- Review WMDA checklists* in advance to:
  - Anticipate type of documents/information that could be requested
  - File scanned documents in a dedicated central location (e.g., a SharePoint, shared drive--use a folder structure to make files easy to locate)
  - Hold mock audits using ZOOM (or platform to be used) to practice screen-sharing, locating files etc

*2020 version of checklists will be used

9

File Review During Audit

Files to be shown to the reviewers via screen-sharing on the platform used for the audit (ZOOM, or registry-hosted alternative)

- Reviewers may not capture any information shown on screen through screenshots or by any other means
- Actual documents will not be transferred to the reviewers through the platform (e.g., through chat feature)
- The ZOOM call will not be recorded

10

Tips for the Reviewers

Use a large screen or even better a two screen environment. That helps you to be able to read all information necessary and having the checklist on a second screen opened to fill it out directly.

11

Tips for the Reviewers

- Be prepared for the remote audit the same way as you are for an on-site visit
- Use a headset for better acoustics on both sides
- Make sure that you are the only person who is able to look at your screen and hear the audit
- Make sure you are not disturbed during the review
- Use video camera so the reviewed person can watch you

12

Remote Audit-File Review Example

The following video clips are excerpts of a staged remote audit of a mock donor VT file using the 'Donor Verification Typing' checklist.
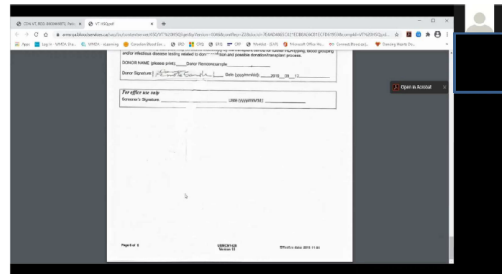
Remote Audit-
VT File Review Intro
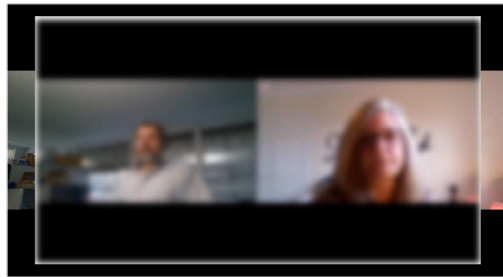
VT File Review-Health Screening
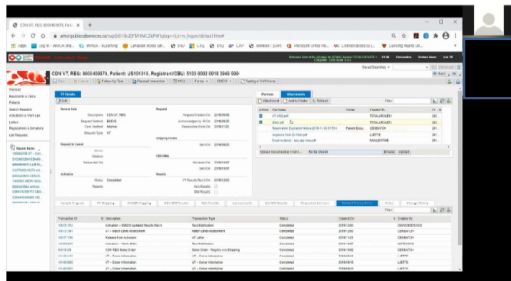
VT File Review-IDMs

Using ZOOM Screen-Sharing

To share your screen with the participants of a ZOOM call:

- Click the 'Share Screen' button located in the meeting controls
- Select to share your entire desktop or a selected file or screen
  - TIP: If sharing entire desktop, close any unnecessary applications and files to prevent unintended sharing

- Click "Stop Share" or "Pause Share" to end or pause screen sharing

ZOOM Support

Detailed information on the ZOOM support page:

https://support.zoom.us/hc/en-us/articles/201362153-Sharing-your-screen-content-or-second-camera

Resources

Registry:
https://share.wmda.info/display/EnsuringQuality/Remote+audits
(includes examples and instructions to prepare virtual registry tour)

Reviewers:
https://share.wmda.info/display/EnsuringQuality/On-site+audits
('Audit Review Plan', 'Guidance for Audit Checklist' contain information for planning remote audit)

Questions

Questions about the remote audit process may be submitted to: accreditation@wmda.info