



# EGALiTE – Accreditation Dossier

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EUROPEAN GROUP FOR ACCREDITATION AND  
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

|                      |                                    |
|----------------------|------------------------------------|
| Date of submission:  | 25.03.2024                         |
| Work package:        | 5- EGALiTE Accreditation Programme |
| Activity Centre:     | EBMT & BST                         |
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# Accreditation Guide (Document 1)

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# EGALiTE – Accreditation Guide

## Accreditation Dossier

### (Document 1)

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# Acronyms:

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|         |                                                                                        |
|---------|----------------------------------------------------------------------------------------|
| B-QM    | Blood Quality Management Programme                                                     |
| BTC     | Blood, Tissues and Cells                                                               |
| CoE     | Council of Europe                                                                      |
| EATCB   | European Association of Tissue and Cell Banks                                          |
| EBA     | European Blood Alliance                                                                |
| EBMT    | European Society for Blood and Marrow Transplantation                                  |
| EC      | European Commission                                                                    |
| ECDC    | European Centre for Disease Prevention and Control                                     |
| EDQM    | European Directorate for the Quality of Medicines and HealthCare                       |
| EEBA    | European Eye Bank Association                                                          |
| EGALITE | European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments |
| ISCT    | International Society for Cellular Therapy                                             |
| JACIE   | Joint Accreditation Committee of the ISCT and the EBMT                                 |
| SoHO    | Substances of Human Origin                                                             |
| WMDA    | World Marrow Donor Association                                                         |

# Disclaimer

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EGALiTE expressly disclaims any responsibility for setting maximum standards and additionally expressly disclaims any responsibility, liability, or duty to member programmes, directors, staff, or programme donors or patients for any such liability arising out of injury or loss to any person by the failure of member programmes, directors, or staff to adhere to the Standards or related guidance.

While the EGALiTE Accreditation Programme encourages the sharing of best practices and recommendations, it does not assume the role of a regulatory body or authority. The EGALiTE Accreditation Programme involves a peer review process designed to assess and evaluate the compliance of SoHO entities with standards and criteria, where experts in the field conduct assessments based on predetermined criteria. The peer review process is conducted with the utmost independence and impartiality to ensure a fair and unbiased evaluation, and the compliance with the best practices.

The EGALiTE Accreditation Programme is not responsible for informing National Competent Authorities of any non-compliance identified during the peer review process, including critical and major non-compliances.

Participants voluntarily engage in this process to demonstrate their commitment to quality and best practices, and organisations participate in the EGALiTE Accreditation Programme voluntarily, acknowledging that the outcomes of the process are not intended for regulatory purposes.

# What is EGALiTE

EGALiTE (European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments) is an EU funded project (European Health and Digital Executive Agency, EU4Health Programme, Project reference number: 101056852) endorsed by leading scientific societies in Europe in the field of Blood, Tissues and Cells (BTC), namely: European Society for Blood and Marrow Transplantation (EBMT), European Blood Alliance (EBA), European Eye Bank Association (EEBA), and the European Association of Tissue and Cell Banks (EATCB).

EGALiTE<sup>1</sup> aims to promote the harmonization of good practices for stakeholders and professionals working in Substances of Human Origin (SoHO) Entities and European expert bodies (namely, European Commission (EC), European Directorate for the Quality of Medicines and HealthCare (EDQM), European Centre for Disease Prevention and Control (ECDC)) in order to foster collaboration and help implement strategies to increase resilience and to ensure continuity and sufficiency of supply and guarantee access to safe and high-quality therapies involving SoHO.

Ultimately, EGALiTE's accreditation seeks to eliminate barriers to SoHO exchanges within EU by certified SoHO Entities to guarantee accessibility and sufficiency.

## What is EGALiTE Accreditation

Accreditation is the process by which defined activities of an organisation are evaluated and recognized by way of impartial and competent evaluators (auditors), as having demonstrated conformity to a specified level of good practice in line with identified standards. The EGALiTE Accreditation Programme is the result of collaboration between SoHO professionals throughout Europe, and is a peer-review process based on a philosophy of support and facilitation.

The applicable Standards for the Accreditation Programme are defined by the EGALiTE's project consortium, composed of experts active in the field, and the auditors, trained and certified are experienced volunteers who work in their respective areas of expertise. The Standards reflect regulatory requirements and international good practice as defined by the Council of Europe (CoE)/EDQM and ECDC, guidance and reference documents produced by scientific societies (i.e. *Joint Accreditation Committee* ISCT-Europe & EBMT (JACIE), World Marrow Donor Association [WMDA]) and practical tools and appraisal methodologies developed by other EU Projects and Joint Actions.

<sup>1</sup> A coalition will be established to manage the outcomes of the EGALiTE Project after the EU funded phase has ended. This coalition will be responsible for managing/administering the accreditation programme. The governance framework of this coalition– Defining mission, vision, values, staff, technical committees, management rules, procedures, and coordination strategies with other accreditation programmes (i.e., articles of association, certificate of incorporation, organisational charts, by-laws, operating agreement, etc.) – will be defined by the coalition partners encompassing the pertinent scientific societies in collaboration with the WP1 working group and will be available by the end of the EGALiTE project.

## Why be accredited?

The EGALiTE Accreditation Programme, based on an independent evaluation of activities, offers SoHO Entities the opportunity for supranational sector/peer recognition for having demonstrated compliance with the quality and safety standards and best practices defined and recognized for SoHO activities at EU level.

It aims to be an effective and trusted warranty of excellence of the activities performed by SoHO organisations in Europe, elevating SoHO programmes to defined performance levels, and at the same time fostering collaboration and exchange of experience and competence between centres and individuals working with diverse SoHO.

EGALiTE accreditation consists in a peer review of practices, and is the mean by which a SoHO Entity can demonstrate compliance with EU-level best practice standards by showcasing its adherence to the required level of practice, and certify that it operates under an effective quality management system. The EGALiTE Accreditation Programme is therefore particularly relevant for organisations that wish to obtain official and identifiable recognition, and be included in an EU network of accredited SoHO Entities to promote EU self-sufficiency and collaborate in the exchange of resources among Member States (either in routine and/or crisis and catastrophic scenarios).

Thus, by being accredited the organisation will:

- Be included in the **EU Network of SoHO Entities able to participate in contingency and sufficiency strategies** defined at EU level – this will allow for the exchange of information and resources among peers;
- Benefit from agile **procedures for the exchange of SoHO**, both at National and EU level – As it provides independent and expert confirmation of compliance with the technical requirements associated with SoHO activities;
- Be able to benefit and **support the Technical Assistance Programme** – which seeks to foster and support SoHO entities in different Member States, thereby enhancing the visibility of your organisation;

Different centres may benefit differently from the EGALiTE Accreditation programme, depending on the scope of their activities.

It is important to note that the EGALiTE Accreditation Programme is a voluntary process by which the operations of an organisation or institution are evaluated according to established standards set by peers in their sector. As such, EGALiTE accreditation is not a legal requirement and does not replace the certification/designation/authorization/licensing activity performed by the Member States Competent Authorities.

## Which Activities can be accredited?

|                                                   | Blood | Tissues | HSC <sup>2,3</sup> |
|---------------------------------------------------|-------|---------|--------------------|
| <b>Generic SoHO Requirements of SoHO Entities</b> | X     | X       | X <sup>2</sup>     |
| <b>Donor Selection</b>                            | -     | X       | X <sup>3</sup>     |
| <b>Donor Registries</b>                           | -     | -       | X <sup>3</sup>     |
| <b>Collection/Procurement</b>                     | -     | X       | X <sup>2</sup>     |
| <b>Testing</b>                                    | -     | X       | X <sup>2</sup>     |
| <b>Processing</b>                                 | -     | X       | X <sup>2</sup>     |
| <b>Distribution</b>                               | -     | X       | X <sup>2,3</sup>   |
| <b>Registries and Vigilance</b>                   | -     | X       | X <sup>2,3</sup>   |
| <b>Clinical Application</b>                       | -     | -       | X <sup>2</sup>     |

## Coordination with other Accreditation Programmes

Since the EGALiTE Accreditation Programme has been developed and implemented in cooperation with major scientific societies, it is compatible and recognizes existing accreditation programmes implemented by these societies, namely: EBMT's JACIE accreditation of haematopoietic stem cell transplantation (HSCT) and cellular therapy and WMDA's certification programme of unrelated hematopoietic stem cell donor registries.

## EGALiTE Standards

The applicable Standards for the EGALiTE Accreditation Programme were developed by the collaborating consortium partners, and are based on:

- **Legal requirements defined in the EU SoHO Legislation:** These are considered the minimum requirements for the authorization of activities of SoHO Entities. These requirements are common for the authorisation and licensing processes performed by the Member State CA.
- **Best European practices:** based on the recommendations and requirements defined in the EDQM Blood and Tissues & Cells Guides, current and future EU Projects and Joint Actions (i.e. EuroGTP II, GAPP JA), and other reference documents produced by the scientific societies (namely JACIE Standards and WMDA Standards) and expert bodies (such as ECDC). Such practices include the procedures associated with vigilance reporting, proposed both in the EU and National Legislations as well as the criteria defined by other initiatives such as the [NOTIFY Library](#) and WMDA SPEAR Reporting.

<sup>2</sup> HSC activities are accredited by JACIE.

<sup>3</sup> Synergy with WMDA Accreditation

- **Quality Management (QM):** QM systems ensure that centres have in place appropriate processes to ensure that professionals are trained and procedures are defined and being carried out in line with agreed standards with the full participation and support from of all staff members. These systems are required to all centres and areas of SoHO, and aim to guarantee good communication, effective common work practices and increased quality and safety of SoHO, and in the end donor and patient protection. It is also a means of rapidly identifying errors or accidents and addressing them so that the impact is correctly assessed, and appropriate actions are taken so possibility of repetition of the problem is minimised. The roles and the responsibilities of all the staff and the training programmes are clearly identified in the QM system.

All the standards are publicly available, and can be used by the centres seeking accreditation for self-assessment of their distinct processes and procedures.

## EGALiTE Accreditation Process

### Minimum requirements for applying for accreditation:

| Volume of Activities                                                                                                                        | Administrative Nature        | Authorisation                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------------|
| Documented experience of continuous operating activities (i.e. QMS activities) of at least twenty four (24) months at the time of applying. | Non for profit organisations | Active authorisation/ license from the relevant CA* |

\*Confirmation that a centre is approved by the national coordination office(s) may be also required.

### How does the accreditation process work?

The accreditation process begins with an application request submitted through the EGALiTE website. Upon receiving this initial registration, the EGALiTE back office initiates the accreditation process. Subsequently, a new form is sent to the applicant, who has 14 days from the acceptance of their registration to submit information related to defining the scope of the accreditation (as outlined in "Submit Application & Checklist" in Figure 1 below).

Once these steps are completed, the EGALiTE Coalition will share the template agreement and the associated quote with the applicant. These documents must be signed by the applicant and will later be countersigned by representatives of the EGALiTE Coalition before being returned to the applicant to finalize their application.

A SoHO Entity seeking accreditation should first carry out a self-assessment of its processes and procedures, relevant to the activities that they wish to be accredited.

This self-assessment allows for the identification of areas that require additional resources, changes in systems or staff training needs to fulfil the accreditation criteria.

When an organisation considers that it meets the criteria, it may then apply for accreditation. Once the application is approved by the EGALiTE Coalition<sup>4</sup>, the centre will be required to prepare and provide a variety of pre-audit information and documentation (e.g. Tissue Establishment Dossier or quality manual or equivalent, including but not limited to a description of the layout of the facility, the quality system and the key activities. A list of SOPs, evidence of staff training, etc.).

When all the pre-audit material has been submitted, EGALiTE will then start with the evaluation of the pre-audit documentation/information as the first step of the accreditation process.

After an evaluation of conformity of these documentation and SOPs with the requirements of the EGALiTE Accreditation Programme, auditors may ask for additional documentation or may proceed directly with the scheduling of an on-site audit. This date is also conditioned by the availability of auditors.

For the on-site assessment the assigned team will be made up of experts conversant with the specific field and the activities that will be assessed. All auditors are duly qualified and have satisfactorily attended the EGALiTE Auditors Training Course (Auditors' requirements are detailed in the section *"Who are the EGALiTE Auditors and how are the Auditor's team assembled"* of this document).

The auditor team will evaluate documentation and records, interview staff and observe procedures in real time.

At the end of the onsite assessment, and before issuing the formal assessment report, auditees and auditors will have the opportunity to meet in order to discuss the audit findings and any outstanding issues (main outcomes, deviations and observations).

A report of the audit will be submitted by the auditors to the EGALiTE Coalition who will collate the information for assessment. Afterwards, a final and detailed report will be sent to the organisation, with recommendations/required actions based on the conclusions of the audit. The SoHO Entity will be able to propose an action plan, commensurate to the auditors' findings.

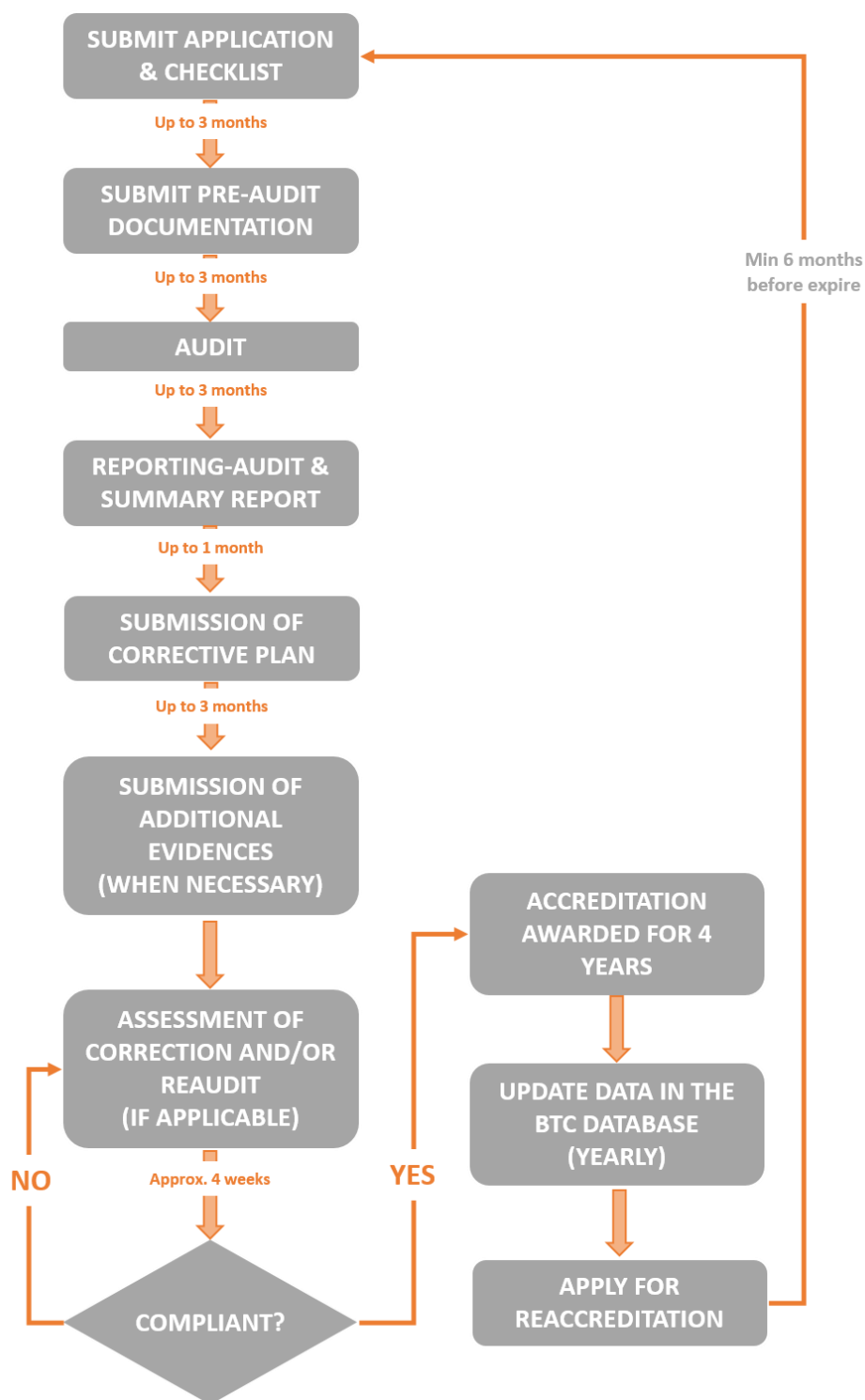
The centre may be required to submit additional documentary evidence of corrections and/or undergo a second audit visit, if needed.

Once all findings have been satisfactorily addressed, the EGALiTE Coalition can award accreditation. Accreditation is awarded for a four-year period, from the date of approval.

The timeframes referred in figure 1 are indicative references and aimed good practices, which may be adjusted to specific situations and agreed with the applicant beforehand, if needed.

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<sup>4</sup> The EGALiTE Coalition manages the outcomes of the EGALiTE Project and is composed of professionals nominated by the EATCB and EEBA.



**Fig.1 – Representation of the EGALITE’s accreditation process**

## Application procedure - Accreditation Platform

As part of our commitment to streamlining processes and ensuring confidentiality, EGALiTE Accreditation Programme utilizes a [digital platform](#) to manage applications and assess standards and requirements. This platform serves as a centralized hub where all data related to the accreditation process is collected and accessible only to assigned auditors, thus ensuring the confidentiality of your application and efficient information management.

Should you have any questions or require further information about the accreditation process or the digital platform, please do not hesitate to contact us. ([EGALiTE@egalite-europe.eu](mailto:EGALiTE@egalite-europe.eu))

## What is a realistic timeframe for the Accreditation Process?

The time from application to accreditation will depend on the size and complexity of the Centre and its activities as well as the amount of time and staff that can be dedicated to the EGALiTE accreditation programme.

It is also important to consider that the accreditation timeframe is highly dependent on the accuracy and detail of the data submitted by the applicant in the newly developed Accreditation Platform. Indicative timeline and the expected duration of the different accreditation steps, are described in figure 1 above.

The [Applicants Guide](#) provides more comprehensive details regarding the whole process.

## Who should be responsible for coordinating EGALiTE Accreditation within my unit?

Applying for EGALiTE accreditation requires planning, time and dedication. It is important to keep this in mind when thinking of submitting an application, especially if this is on top of a high workload. Depending on the centre, the person who takes responsibility for coordinating an application to the EGALiTE Accreditation Programme could be a Quality Manager, an administrative assistant or someone who is capable of understanding the requirements of the Accreditation Programme.

On the application form, you are asked to nominate one person as the EGALiTE contact. It is very important that EGALiTE has only one main contact to avoid duplication and miscommunication.

# Who are the EGALiTE Auditors and how is the Audit team assembled?

The assignment of auditors is carried out by the EGALiTE Coalition, following pre-defined criteria outlined in the document '[Auditor Job Description](#).'

EGALiTE Auditors are volunteer experts of the different areas of SoHO, who have been duly trained and certified by EGALiTE's training programme.

EGALiTE auditors have the following characteristics: an open-minded approach to audits and standards; a commitment to EGALiTE (standards, processes, deadlines); team spirit; and good communication and interpersonal skills; are experienced, independent, and respecting of confidentiality.

## Audit Team:

The audit teams typically include a technical expert conversant with the specific SoHO being investigated and an auditor familiar with the Generic SoHO Standards. The final number of auditors will depend on the number of sites within the applicant organisation, and whether the audit includes different SoHO. One auditor will also be assigned the role of team liaison. If needed, observers/trainees and/ or language facilitators can be included in the team. Some auditors may be qualified to audit more than one SoHO field. Generally, the audit team comprises two auditors, with the liaison auditor responsible for assessing the Generic EGALiTE Standards. However, exceptions may arise based on the auditors' diverse profiles. For instance, if EGALiTE-certified auditors are unavailable for specific SoHO activities, a technical expert will be invited to participate in the assessment.

There are specific entry requirements for would-be auditors and defined in the '[Auditor Job Description](#)' for the different audit roles (Liaison Auditor, Auditors and observers/trainees.).

## Minimum Qualifications and Requirements

An auditor requires extensive expertise in the subject matter to be able to identify problems and must also be a competent auditor without any conflict of interests (with the entity under accreditation).

The auditor shall hold a professional degree in the field of medical or biological sciences, and five years' experience as a Responsible Person, Medical Director, Supervisor of SoHO Entity's activities, Heads of Production, or Heads of specific SoHO Departments. Other roles may be accepted when a letter from the Responsible Person confirms his/her suitable experience in the relevant SoHO activities.

Each auditor shall have completed a training course for new auditor, passed the associated exam based on the EGALiTE Standards and complete periodic auditors training modules as prepared by EGALiTE.

The auditor shall complete and sign a statement to the effect that she/he is qualified by scientific training and experience to be an EGALiTE auditor, additionally non-disclosure agreements are also signed by the audit team at the beginning of the accreditation process.

The auditors are members of EATCB, EEBA, or similar society or association.

## How much does it cost & what are the terms and conditions?

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The EGALiTE fees are based on the number of activities included in the scope of the accreditation (e.g. Donation & Collection; Processing, storage and release; Distribution, registries and vigilance).

Full details of fees and terms and conditions can be found on [EGALiTE website](#).

## Applicants Guide (Document 2)

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# EGALiTE – Applicants Guide

## Accreditation Dossier (Document 2)

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EUROPEAN GROUP FOR ACCREDITATION AND  
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

|                      |                               |
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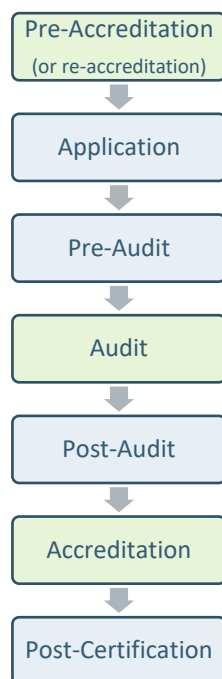
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# Introduction

This Guide has been produced to assist applicants prepare for the EGALiTE Accreditation. The document should be read in conjunction with the current [EGALiTE Accreditation Guide](#).

This Guide has been defined in accordance to the accreditation process defined by EGALiTE, and includes the following sections:



## 1. Pre-Accreditation

### Submission of Application

Before submitting an application for accreditation, the applicant should ensure that they can clearly demonstrate compliance in all areas of the Accreditation Manual and the applicable [EGALiTE Standards](#).

Standards and *Checklist* are made publicly available, and should be used by the organisations to determine their compliance level, before the submission of the application.

#### Please note:

- Gather evidence during this self-assessment. This will be useful for the following steps of the accreditation process.
- First time applicants should provide the filled in *Application form* (including the SoHO Establishment Dossier) and the *Checklist*.



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- Centres applying for Reaccreditation just need to submit the filled in *Application form*

## Application Form

When completing the Application form, the applicant should:

- Include the most up to date information;
- Pay special attention when defining the layout of the activities and organisation (Scope i.e. activities to be accredited, number of sites, details of the Quality Management System, etc);
- A SoHO Establishment Dossier (former Tissue Establishment Dossier) shall gather the minimum information related with the applicant's organisation, and must be included as annex of the Application Form;
- Review that no sections have been left empty;

The information provided in the application form by the applicants will determine invoicing, composition of the audit team, scope of accreditation, location of the units (once the scope is set/approved no modifications will be allowed after the signature of the agreement).

## Self-Assessment Checklist

Applicants should send a completed *self-assessment checklist* together with the Application form. This procedure is completed within the [Accreditation Platform](#).

Applicants should self-assess compliance against all standards under the scope of their accreditation request and indicate if they are compliant, non-compliant, partially compliant or if the Standard is not applicable. Applicant should make sure that they are able to document how they meet each standard, for example by referring to a specific SOP, training record, meeting record, etc. These references and other information should be entered into the *self-assessment checklist* to help the auditor easily find supporting documents and evidence of compliance with the standards.

It is especially relevant to indicate the reason(s) why Standards are Not applicable, Partially Complied or Non-Complied with.

### Please note:

- Applicants may need to involve different professionals to complete the *self-assessment checklist*
- The Application form and self-assessment checklist will be reviewed by the EGALiTE Coalition, and the applicant will be contacted should any clarifications be needed.
- EGALiTE fees are available at the [EGALiTE's website](#)



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## Signing the Standard Agreement

Once the application has been pre-approved by the EGALiTE Coalition, the applicant will be asked to sign a Standard agreement. By signing the agreement, the centre accepts the quotation determined and provided by the EGALiTE.

Once the Standard agreement has been signed by both the Applicant and EGALiTE, the application will be considered approved. The applicant should not pay the Quotation attached to the agreement at this stage. The invoicing and payment will be later managed by EGALiTE, before the audit.

### **Please note:**

The applicant should sign and return the Standard Agreement to the EGALiTE within 30 days of receiving it.

When more time is needed to complete this task, the applicant should let the EGALiTE know in advance. Delays at applicant's end will impact the progress of the accreditation process.

## Preparing the pre-audit documentation

Documentation and any sensitive data submitted by the applicants will be stored in an electronic database owned by EATCB and EEBA, which will be located in the European Economic Area (EEA). Auditors collaborating with the EGALiTE Programmes have signed Non-Disclosure Agreements (NDAs) and are obligated to maintain confidentiality regarding all information assessed during the accreditation procedures.

## Documentation

The applicant should provide all the documents required according to the standards "evidence", by uploading them on the Accreditation Platform.

The selected documentation should be the latest version available and up to date

When an applicant cannot or does not need to provide a document for a specific item, they should indicate the reason for this in the Accreditation Platform.

It is the responsibility of the centre to ensure that the documentation provided to EGALiTE has appropriate security measures in place before the transfer and to make certain that the respective national laws are compiled with.

Staff at the EGALiTE Administrative Office will check the folder contents to make sure that a file or document is present, without assessing the quality of the documentation. If documents appear to be missing, the EGALiTE Administrative Office will contact the centre.

The applicant is responsible to send any updated documents to the EGALiTE Administrative Office before the audit.



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**Please note:**

- To complete the pre-audit documentation, get the whole team on board.

The pre-audit documentation should preferably be prepared in English, only as an exception it can be provided in the language of the centre.

In those cases where there are no auditors that speak the language of the centre available, the applicant will have to translate a list of documents into English. The translation is not aimed to be from a professional translator but is a gesture within EGALiTE's auditors' capacity (revised automatic translations, namely the free *eTranslation* neural machine translation service provided by the European Commission, are accepted).

The completed pre-audit documentation (Checklist and evidence documents) should be provided to the EGALiTE Coalition within 90 days after the Standard Agreement has been signed by both parties. Approximately two months prior to the audit applicants will be requested to update the pre-audit documentation, in case there have been any significant changes.

The files are also stored electronically by the EGALiTE Coalition in the Accreditation Platform. Only EGALiTE Staff have access to those documents. However, during the accreditation process the auditors assigned to the centre, and the EGALiTE Coalition will be involved and have access to information related to the application.

## Preparing for the audit

Once the pre-audit documentation has been received, and to start programming the audit, the EGALiTE Coalition will ask the applicant to prepare and submit the following:

- Set of preferred dates for audit (pending auditors' availability and pre-audit documentation approval)
- Notification of any auditors who the applicant would prefer not to participate in the audit due to potential conflict of Interest (please provide name, last name and the reason why there is a conflict of interest)
- Additional documents, if required by the auditors up until two weeks prior to the audits.

### Onsite audit:

- Recommendations of accommodation for the audit- team in a convenient and reasonably-priced hotel
- Information for the auditors on how to get to the facility. When possible, make arrangements to pick up the team at their hotel. Otherwise, provide information about available transportation and estimate time that will be required to reach the facility to be audited.
- Reservation of a room for the auditors for the duration of the audit for reviewing case notes, procedures, manuals and documents. In addition, reservation of a room for the opening and closing meetings and the interviews, that is adequate in size to accommodate the entire audit team, key organisation personnel and others that the team wishes to invite.



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- Arrangement of a modest business lunch for the audits team, would be appreciated as audit teams may want to utilise the lunch hour as a working lunch.
- Provide Wi-Fi connection for auditors.

The audit teams typically include a technical expert conversant with the specific SoHO being investigated and an auditor familiar with the Generic SoHO Standards. The final number of auditors will depend on the number of sites within the applicant organization, and whether the audit includes different SoHO. One auditor will also be assigned the role of team liaison. Once the Liaison Auditor is defined, the applicant will receive the Audit Plan, indicating the different Auditors and their roles, and the agenda with the schedule to be followed during the Audit.

## 2. Audit

The audit will follow the agenda indicated in the Audit Plan.

In those cases where there are no auditors available that speak the language of the centres and the audit needs to be conducted in English, the centre will have to identify facilitators. The facilitators do not need to be professional translators, but preferentially (and when possible) are not directly involved in the activities under evaluation.

### Opening meeting

- Should include all key personnel of the SoHO Establishment and members of the Audit Team
- The Responsible Person or other designated personnel should plan to introduce the members of the applicant SoHO Entitie(s), and present any other information to the audit team about the activities that may be helpful, particularly any information that was not required on the checklist or required documents list. It is helpful to review the structure and organisation of the SoHO Entity and the location of the different sites (if applicable), particularly if these issues are complex and/or there are any off-site locations. This presentation should not exceed 10-15 minutes.

### During the audit

- Each audit team member should have a knowledgeable member of staff available at all times to answer questions, find documents or procedures, etc. Appropriate individuals would include a quality manager, data manager, laboratory supervisor, and technicians.
- The following documents must be immediately available for the auditors to review:
  - Complete SOP manual for the activities under the scope of the audit.
  - Documentation of training and competency assessment of the staff (initial and continuous).
  - Quality assessment and continuous improvement documents, including internal audit reports.
  - Validation studies.
  - Other documentation related to the activities



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- Be prepared to have someone escort the auditors to each of the sites during the onsite audit. If there are distant sites, be prepared to transport the auditors there and accompany them at those sites.
- Auditors will need to talk to key personnel at each of the sites. Be certain that they will be available during the scheduled time of the visit for each of the sites. For example, Donation Centre staff, including physicians, nurses and any additional administrative personnel who are needed to answer specific questions on the checklist.
- Be prepared to gather additional documentation requested by the team during the time that they are present in your facility. If sent later, it would delay the final report.

## Closing meeting

- At the end of the audit, the auditors may wish to meet privately with the Responsible Person and/or designated personnel if there are issues to be raised that may be of a sensitive or confidential nature. Be available for this meeting
- The purpose of the closing meeting is to allow the auditors to summarise their major findings and to outline the accreditation process. Remember that the Audit Report observations are reviewed by the EGALiTE Coalition who will confirm the suitability of the conclusion and actions proposed by the audit team.

## 3. Post-Audit

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### After the Audit

Once the Audit is completed, the applicant will receive an Audit Evaluation form (issued by the IT Accreditation Platform). The form should be used by the applicant to formally state satisfaction or to raise any issues that may have occurred during the audit visit. It also gives the applicant an opportunity to give feedback on the process overall. It is important that this form be returned as quickly as possible. The evaluation by the centre will also be sent to the auditors for their information and response where necessary.

Feedback and complaints can also be sent to [EGALiTE@egalite-europe.eu](mailto:EGALiTE@egalite-europe.eu) at any other time during the process.

### Summary Report

Once the Auditors have submitted the completed Audit Report and the Audit Checklist to the EGALiTE Coalition, these will be reviewed and analysed. Sporadically, clarification may be required from the centre during this phase.

Once the EGALiTE Coalition has assessed the level of compliance, the Summary Report and Checklist will be sent back to the applicant.



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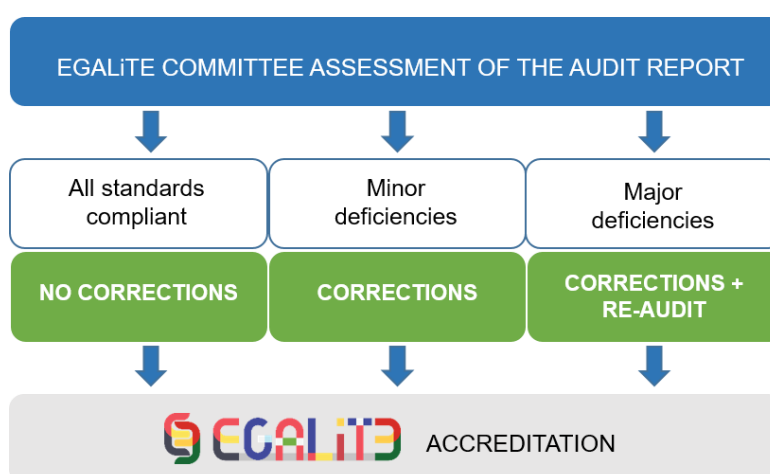
## Corrective Plan and Evidence of Corrections

The Summary Report and Checklist will identify those areas that were found to have deficiencies : the IT Accreditation Platform provides a tool to report on compliance, noncompliance and partial compliance of the different requirements.

The applicant will have the chance to work on these deficiencies and will have to send further evidence to demonstrate that they have been corrected. The applicant will receive instructions on how to provide their response.

Once documentary evidence of corrections is submitted, this will be reviewed by the original audit team. If this evidence is satisfactory and the centre has achieved full compliance, a final recommendation for accreditation will be sent to the EGALiTE Coalition for approval

## Potential Audit outcomes



In some cases, a second audit may be required to look at a very specific aspect of the activities or where a wider review is necessary. This will be arranged by the EGALiTE Coalition on a date that is convenient for the applicant centre and the auditors but should take place within 1 year of the initial Audit Report being issued.

Costs arising from the focussed re-audit will be payable by the centre. These costs will be limited to the auditors' travel, accommodation and subsistence costs.

The timeline for submitting the evidence of corrections will be stated in the Summary report. Centres are asked to submit their corrective plan within 1 month and evidences of corrections within 3 months (when applicable) after receiving the Summary Report. If that is not possible, the applicant should submit a summary of any issues that may delay or obstruct corrections and estimate the time required for consideration by EGALiTE Coalition.

It is important to highlight that, due to the potential impact of major and critical deficiencies, shorter timeframes may be defined to correct deficiencies found during the audit. For example, auditors may suggest



urgent corrections to be implemented immediately after the audit, in order to facilitate the progression of the accreditation process.

Where an applicant delays more than 12 months in demonstrating full compliance with the EGALiTE Standards after receiving the Summary Report, the accreditation process of the centre will be considered expired and the centre will have to restart the process. The calculation of 12 months will be made from the date when the Summary Report was emailed from the EGALiTE Administrative Office to the applicant.

## Receiving the Accreditation Letter and Certificate

Once the centre has been granted Accreditation, it will be listed in the List of Accredited Centres in the EGALiTE website.

A DRAFT version of the Accreditation Letter and Certificate will be sent to the applicant, who should check whether all details are correct or modifications are needed and communicate these to their EGALiTE contact. Subsequently, the applicant will receive hard copies of the Accreditation Letter and Certificate.

Additionally, the applicant will receive the EGALiTE accredited logo and the guideline for its use. This logo is to be used strictly for the accredited units/activities of the organisation only.

Please note that in order to grant the accreditation the centre has to be up to date with the payment of the accreditation fees.

## 4. Post Certification

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### BTC Database

As defined in the EGALiTE Standards, accredited entities are requested to keep up to date information in the BTC Database. This requirement aims to ensure the functionality of the EGALiTE network, thus promoting the collaboration between stakeholders and the swift cooperation for the implementation of contingencies, during crisis.

### Surveillance

During the period of the accreditation the EGALiTE Coalition might contact the entity to perform some surveillance activities in order to assess the maintenance of the Quality Management system.

### Ceased of the accredited activities

Accredited centres are required to proactively inform EGALiTE Coalition in case of ceasing of activities within the scope of the issued accreditation.



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## Reaccreditation

It is recommended that proceedings for reaccreditation are initiated 6 months prior to expiry in order to minimize the possibility of lapses between accreditation expiry and reaccreditation. Please bear in mind that such lapses are subject to the timing of document submission, availability of auditors, the findings of the audit and the applicant's submission of documentary evidence of corrections.



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## Application Form (Document 3)

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# EGALiTE – Application Form

## Accreditation Dossier (Document 3)

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EUROPEAN GROUP FOR ACCREDITATION AND  
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

|                      |                                    |
|----------------------|------------------------------------|
| Date of submission:  | 25.03.2024                         |
| Work package:        | 5- EGALiTE Accreditation Programme |
| Activity Centre:     | EBMT & BST                         |
| Dissemination level: | Public                             |



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# APPLICATION FORM – ACCREDITATION

## Instructions for completing this Application Form

INITIAL ACCREDITATION (first time applying): SoHO entities applying for the first time must submit the completed Inspection Checklist (self-assessment checklist) and/or the SoHO Establishment Dossier (or equivalent), together with this Application Form.

| 1. GENERAL DETAILS                                 |  |
|----------------------------------------------------|--|
| Programme Name/<br>Institution name <sup>1</sup> : |  |
| Country:                                           |  |
| Working Language<br>of the Centre:                 |  |

| 1.1. Contact Details                                                                                                                                                                                                                                                                                  |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| There should be one designated person responsible for contact with EGALITE. Their details should be provided below. The applicant is responsible for ensuring that any changes to contact information are promptly communicated to EGALITE. Failure to do so may result in delays during the process. |                              |
| Title:                                                                                                                                                                                                                                                                                                |                              |
| First Name:                                                                                                                                                                                                                                                                                           |                              |
| Family Name:                                                                                                                                                                                                                                                                                          |                              |
| Institution:                                                                                                                                                                                                                                                                                          |                              |
| 1.1.1. Details of the organisation                                                                                                                                                                                                                                                                    |                              |
| EU SoHO Entity<br>CODE                                                                                                                                                                                                                                                                                | EU compendium/ authorisation |
| Official Address:                                                                                                                                                                                                                                                                                     |                              |

<sup>1</sup> Programme name should be used to describe an application including where there are multiple sites, departments, facilities or institutions. **Note that this is the name that will appear on the eventual certificate of accreditation.**

|                                  |  |
|----------------------------------|--|
| (incl. Post Code, City, country) |  |
| Phone:                           |  |
| E-mail:                          |  |

|                                            |  |
|--------------------------------------------|--|
| <b>1.2. Responsible Person<sup>2</sup></b> |  |
| fill if only different from section 1.1.   |  |
| Title:                                     |  |
| First Name:                                |  |
| Family Name:                               |  |
| Institution:                               |  |
| E-mail:                                    |  |

*The Personal Data provided will be used for the purpose of management of the Pilot Actions foreseen in the context of the EGALITE project and processed according to the General Data Protection Regulation (GDPR 2016/679). The data will be stored in an electronic database property of BST and ONT which will be allocated in the EEA (European Economic Area) or in countries that are provided with the same level of protection for privacy.*

*Data Subjects have the right of access, rectification, erasure, restriction, portability, and objection to the processing of his or her personal data. If you wish to exercise any of the rights listed above, please write to [Egalite@egalite-europe.eu](mailto:Egalite@egalite-europe.eu).*

|                                                                                                       |  |
|-------------------------------------------------------------------------------------------------------|--|
| <b>1.3. Invoicing Information</b>                                                                     |  |
| Institution:                                                                                          |  |
| Official Address:<br>(Incl. Post Code, City, country) <b>fill if only different from section 1.1.</b> |  |
| Phone:                                                                                                |  |
| E-mail:                                                                                               |  |
| VAT Number <sup>3</sup> :                                                                             |  |

<sup>2</sup> Means the nominated individual in a SoHO entity that has responsibility for SoHO release

<sup>3</sup> VAT (Value Added Tax) is the number used for tax purposes and is applied to sales of goods and services. The VAT number should refer to the entity that will pay the accreditation fee. It may be called something different in each country.

|                                                                                                                    |  |
|--------------------------------------------------------------------------------------------------------------------|--|
| <b>Scientific Society Membership:</b><br><br>(No / Yes, individual or institutional and which scientific society ) |  |
| <b>Any other relevant information related to invoice:</b>                                                          |  |

| 2. SUMMARY OF ORGANISATION OF THE ACTIVITIES                                    |                   |  |                                               |  |
|---------------------------------------------------------------------------------|-------------------|--|-----------------------------------------------|--|
| 2.1. Accreditation Scope                                                        |                   |  |                                               |  |
| Activity(ies) for which you are requesting accreditation (mark as appropriate): |                   |  |                                               |  |
| Area                                                                            | Donor             |  | Type of SoHO                                  |  |
| Donor Selection, donation & Collection                                          | Living Autologous |  | Adipose tissue                                |  |
|                                                                                 |                   |  | Amniotic Membrane                             |  |
|                                                                                 |                   |  | Cardiovascular                                |  |
|                                                                                 | Living Allogenic  |  | Cord Blood                                    |  |
|                                                                                 |                   |  | Musculoskeletal                               |  |
|                                                                                 |                   |  | Nerves                                        |  |
|                                                                                 |                   |  | Ocular Tissues                                |  |
|                                                                                 | Deceased Donor    |  | Blood components for topical use or injection |  |
|                                                                                 |                   |  | Skin                                          |  |
|                                                                                 |                   |  | Others (Breast Milk, faecal microbiota, etc)  |  |
| Processing, Storage and Release                                                 |                   |  | Adipose tissue                                |  |
|                                                                                 |                   |  | Amniotic Membrane                             |  |
|                                                                                 |                   |  | Cardiovascular                                |  |
|                                                                                 |                   |  | Cord Blood                                    |  |
|                                                                                 |                   |  | Musculoskeletal                               |  |
|                                                                                 |                   |  | Nerves                                        |  |
|                                                                                 |                   |  | Ocular Tissues                                |  |
|                                                                                 |                   |  | Blood components for topical use or injection |  |
|                                                                                 |                   |  | Skin                                          |  |
|                                                                                 |                   |  | Others (Breast Milk, faecal microbiota, etc)  |  |
| Distribution, Registries and Vigilance                                          |                   |  | Adipose tissue                                |  |
|                                                                                 |                   |  | Amniotic Membrane                             |  |
|                                                                                 |                   |  | Cardiovascular                                |  |
|                                                                                 |                   |  | Cord Blood                                    |  |
|                                                                                 |                   |  | Musculoskeletal                               |  |
|                                                                                 |                   |  | Nerves                                        |  |
|                                                                                 |                   |  | Ocular Tissues                                |  |
|                                                                                 |                   |  | Blood components for topical use or injection |  |
|                                                                                 |                   |  | Skin                                          |  |
|                                                                                 |                   |  | Others (Breast Milk, faecal microbiota, etc)  |  |



## 2.2. Facilities

Number of different sites to be included in the accreditation.

|                                                              | Number of sites | Name and location(s) of the site(s) |
|--------------------------------------------------------------|-----------------|-------------------------------------|
| <b>Total number of sites<sup>4</sup>:</b>                    |                 |                                     |
| Number of Donation Centres <sup>5</sup> :                    |                 |                                     |
| Number of Donation sites <sup>6</sup> :                      |                 |                                     |
| Number of Processing Facilities:                             |                 |                                     |
| Number of Classified Areas within the processing facilities: |                 |                                     |

## 2.3. Description of the interaction between Donation and Processing Facilities

Please indicate the distance between the different facilities/sites. Please describe the accessibility (e.g. average time, and preferable transportation mode between sites, etc). If possible, please add an organizational chart depicting the relationship between facilities & sites.

|                                                            |  |
|------------------------------------------------------------|--|
| Collection Site → Donation Centre                          |  |
| Donation Centre → Processing Facilities/SoHO Establishment |  |
| Other relevant information:                                |  |

<sup>4</sup> Total number of sites directly related with the activities to be included in the accreditation programme (i.e. one SoHO Establishment can have more than one processing facilities and Donation Centre(s)). Different institutions where only collection/procurement is performed by SoHO entity/Donation Centre's Staff, shall not be included in this field.

<sup>5</sup> Means a SoHO Entity that carries out one or more of the activities: SoHO donor history review and eligibility assessment; SoHO testing of donors for eligibility or matching purposes; collection of SoHOs from donors or patients; SoHO entity that that does donation activities.

<sup>6</sup> i.e. one Donation Centre can coordinate activities in different Donation Sites (example: different Hospitals)



## 2.4. Quality Management System (QMS)

Please click the corresponding option:

- ☐ There is one integrated QMS across the entire programme (Donation, Collection, Processing and Distribution)
- ☐ There is more than one QMS across the programme. Please describe:

## 2.5. Services provided/outsourced by 3<sup>rd</sup> parties:

Please click the corresponding options:

- ☐ Donation
- ☐ Collection / Procurement
- ☐ Testing
- ☐ Processing (indicate the activity (i.e. irradiation, freeze drying, etc.) \_\_\_\_\_)
- ☐ Storage
- ☐ Distribution
- ☐ Transport
- ☐ Other ( \_\_\_\_\_ )



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Please fill in the data included in the relevant sections, according the Accreditation goals and scope defined in section 2.1.

|                                                                                                                      |  |
|----------------------------------------------------------------------------------------------------------------------|--|
| <b>3. DONOR SELECTION, DONATION AND COLLECTION</b> (fill in only when applicable, and if different from section 1.1) |  |
| <b>3.1. Facility details</b>                                                                                         |  |
| <b>Institution Name:</b>                                                                                             |  |
| <b>Official Address:</b><br>(incl. Post Code, City, country) <b>fill if only different from section 1.1.</b>         |  |

|                                                                                                           |                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>3.2. Volume of activities in the previous year</b>                                                     |                                                                                                                                                                                                                                       |
| <b>Number of Donors:</b>                                                                                  | <b>Number of living donors</b> (if applicable):<br><b>Number of deceased donors</b> (if applicable):                                                                                                                                  |
| <b>Number of units of SoHO donated</b><br>(See definitions in the <a href="#">EDQM's Recommendation</a> ) | Adipose tissue:<br>Amniotic Membrane:<br>Cardiovascular:<br>Cord Blood:<br>Musculoskeletal:<br>Nerves:<br>Ocular Tissues:<br>Blood components for topical use or injection:<br>Skin:<br>Others (Breast Milk, faecal microbiota, etc): |



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### 3.3. Key Personnel

| Position                                                              | Title | 1 <sup>st</sup> Name | Family Name | Qualifications | Number of years of experience in SoHO activities |
|-----------------------------------------------------------------------|-------|----------------------|-------------|----------------|--------------------------------------------------|
| <b>Responsible Person (RP)</b><br>fill if different from section 1.1. |       |                      |             |                |                                                  |
| <b>SoHO Physician</b> (if different from RP)                          |       |                      |             |                |                                                  |
| <b>Quality Manager</b>                                                |       |                      |             |                |                                                  |
| <b>Other Key Personnel</b>                                            |       |                      |             |                |                                                  |
|                                                                       |       |                      |             |                |                                                  |
|                                                                       |       |                      |             |                |                                                  |
|                                                                       |       |                      |             |                |                                                  |

### 3.4. Is your organization accredited, licensed or authorised by any Regulatory organization/ Competent Authority?

Please click the corresponding option:

- ☐ Yes, (date of licensing, name of the Regulatory organization/ Competent Authority, number of authorisation (if applicable)):
- \_\_\_\_\_
- \_\_\_\_\_
- ☐ No

### 3.5. In which laboratory(s) / facility(s) are tests performed on the donor's samples, other than those tests performed by the processing facility described in this application?

### 3.6. Is this testing laboratory(s) / facility(s) accredited, licensed or authorised by any other organisation (regulatory)?

- ☐ Yes, name of the Regulatory organization/ Competent Authority: \_\_\_\_\_



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☐ No

### 3.7. Which SoHO entity does your Donation Centre supply?

Please complete the information below even if all fall under the same organisation.

Please fill the data included in the relevant sections, according the Accreditation goals and scope defined in section 2.1.

## 4. PROCESSING, STORAGE AND RELEASE (fill only when applicable, and if different from section 1.1)

### 4.1. Facilities Details

**Institution Name:**

**Official Address:**

(incl. Post Code, City, country) **fill if only different from section 1.1.**

### 4.2. Volume of activities in the previous year

**Number of SoHO units released for clinical application (distributed or not)**

(See definitions in the [EDQM's Recommendation](#))

Adipose tissue:  
Amniotic Membrane:  
Cardiovascular:  
Cord Blood:  
Musculoskeletal:  
Nerves:  
Ocular Tissues:  
Blood components for topical use or injection:  
Skin:  
Others (Breast Milk, faecal microbiota, etc):



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#### 4.3. Key Personnel

| Position                                                                   | Title | 1 <sup>st</sup> Name | Family Name | Qualifications | Number of years of experience in SoHO activities |
|----------------------------------------------------------------------------|-------|----------------------|-------------|----------------|--------------------------------------------------|
| <b>Responsible Person (RP)</b><br>fill if only different from section 1.1. |       |                      |             |                |                                                  |
| <b>SoHO Physician</b> (if different from RP)                               |       |                      |             |                |                                                  |
| <b>Quality Manager</b>                                                     |       |                      |             |                |                                                  |
| <b>Other Key Personnel</b>                                                 |       |                      |             |                |                                                  |
|                                                                            |       |                      |             |                |                                                  |
|                                                                            |       |                      |             |                |                                                  |
|                                                                            |       |                      |             |                |                                                  |
|                                                                            |       |                      |             |                |                                                  |

#### 4.4. Is your organization accredited, licensed or authorised by any Regulatory organization/ Competent Authority?

Please click the corresponding option:

- ☐ Yes, (date of licensing, name of the Regulatory organization/ Competent Authority, number of authorisation (if applicable)):
- \_\_\_\_\_
- \_\_\_\_\_
- ☐ No

#### 4.5. In which laboratory(s) / facility(s) are tests performed on the donor's samples or SoHO quality controls, other than those tests performed by the processing facility described in this application?



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|                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>4.6. Which Donation Centres or Collection sites supply your SoHO entity?</b><br>Please complete the information below even if all fall under the same organisation. |
|                                                                                                                                                                        |

Please fill the data included in the relevant sections, according to the Accreditation goals and scope defined in section 2.1.

|                                                                                                              |  |
|--------------------------------------------------------------------------------------------------------------|--|
| <b>5. DISTRIBUTION</b> (fill only when applicable, and if different from section 1.1)                        |  |
| <b>5.1. Facility Details</b>                                                                                 |  |
| <b>Institution Name:</b>                                                                                     |  |
| <b>Official Address:</b><br>(incl. Post Code, City, country) <b>fill if only different from section 1.1.</b> |  |

|                                                                                                                                                      |                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>5.2. Volume of activities in the previous year</b>                                                                                                |                                                                                                                                                                                                                                       |
| <b>Number of SoHO units Distributed to end users or other SoHO Establishments</b><br>(See definitions in the <a href="#">EDQM's Recommendation</a> ) | Adipose tissue:<br>Amniotic Membrane:<br>Cardiovascular:<br>Cord Blood:<br>Musculoskeletal:<br>Nerves:<br>Ocular Tissues:<br>Blood components for topical use or injection:<br>Skin:<br>Others (Breast Milk, faecal microbiota, etc): |



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### 5.3. Key Personnel

| Position                                                                                  | Title | 1 <sup>st</sup> Name | Family Name | Qualifications | Number of years of experience in SoHO activities |
|-------------------------------------------------------------------------------------------|-------|----------------------|-------------|----------------|--------------------------------------------------|
| <b>Responsible Person (RP)</b><br><small>fill if only different from section 1.1.</small> |       |                      |             |                |                                                  |
| <b>Physician</b> (if different from RP)                                                   |       |                      |             |                |                                                  |
| <b>Quality Manager</b>                                                                    |       |                      |             |                |                                                  |
| Other Key Personnel                                                                       |       |                      |             |                |                                                  |
|                                                                                           |       |                      |             |                |                                                  |
|                                                                                           |       |                      |             |                |                                                  |
|                                                                                           |       |                      |             |                |                                                  |
|                                                                                           |       |                      |             |                |                                                  |

### 5.4. Is your organization accredited, licensed or authorised by any Regulatory organization/ Competent Authority?

Please click the corresponding option:

- ☐ Yes, (date of licensing, name of the Regulatory organization/ Competent Authority, number of authorisation (if applicable)):
- \_\_\_\_\_
- \_\_\_\_\_
- ☐ No



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**5.5. Which SoHO entity supply your organisation?** (to be filled only if your organization distributes SoHO processed by 3<sup>rd</sup> parties)

|  |
|--|
|  |
|--|

**Additional Information:**

Please add any additional information that you may find relevant

|  |
|--|
|  |
|--|



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## Audit Procedure & Auditors Guidance (Document 4)

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# EGALiTE – Audit Procedure & Auditors Guidance

## Accreditation Dossier (Document 4)

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EUROPEAN GROUP FOR ACCREDITATION AND  
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

|                      |                                    |
|----------------------|------------------------------------|
| Date of submission:  | 25.03.2024                         |
| Work package:        | 5- EGALiTE Accreditation Programme |
| Activity Centre:     | EBMT & BST                         |
| Dissemination level: | Public                             |



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This procedure has been defined based on the contents and defined in the JACIE Auditor Handbook<sup>1</sup> and JACIE Guide<sup>2</sup>. It aims to be the best reference for auditors to help guide them through all the stages of an EGALiTE audit.

## Introduction

EGALiTE Auditors are volunteers who work in the field of the Substances of Human Origin (SoHO), in quality management (QM), or with other scientific roles, namely: Responsible Persons, Medical Directors, Heads of Production, Heads of specific SoHO Departments, etc. Other roles may be accepted when a letter from the Responsible Person confirms his/her suitable experience in the relevant SoHO activities.

There are specific entry requirements for would-be auditors and defined job descriptions for the different audit roles. Some auditors may be qualified to audit more than one activity. For example, a Responsible person might be qualified to audit both collection and processing facilities. All auditors are asked to performing 1 audit per year.

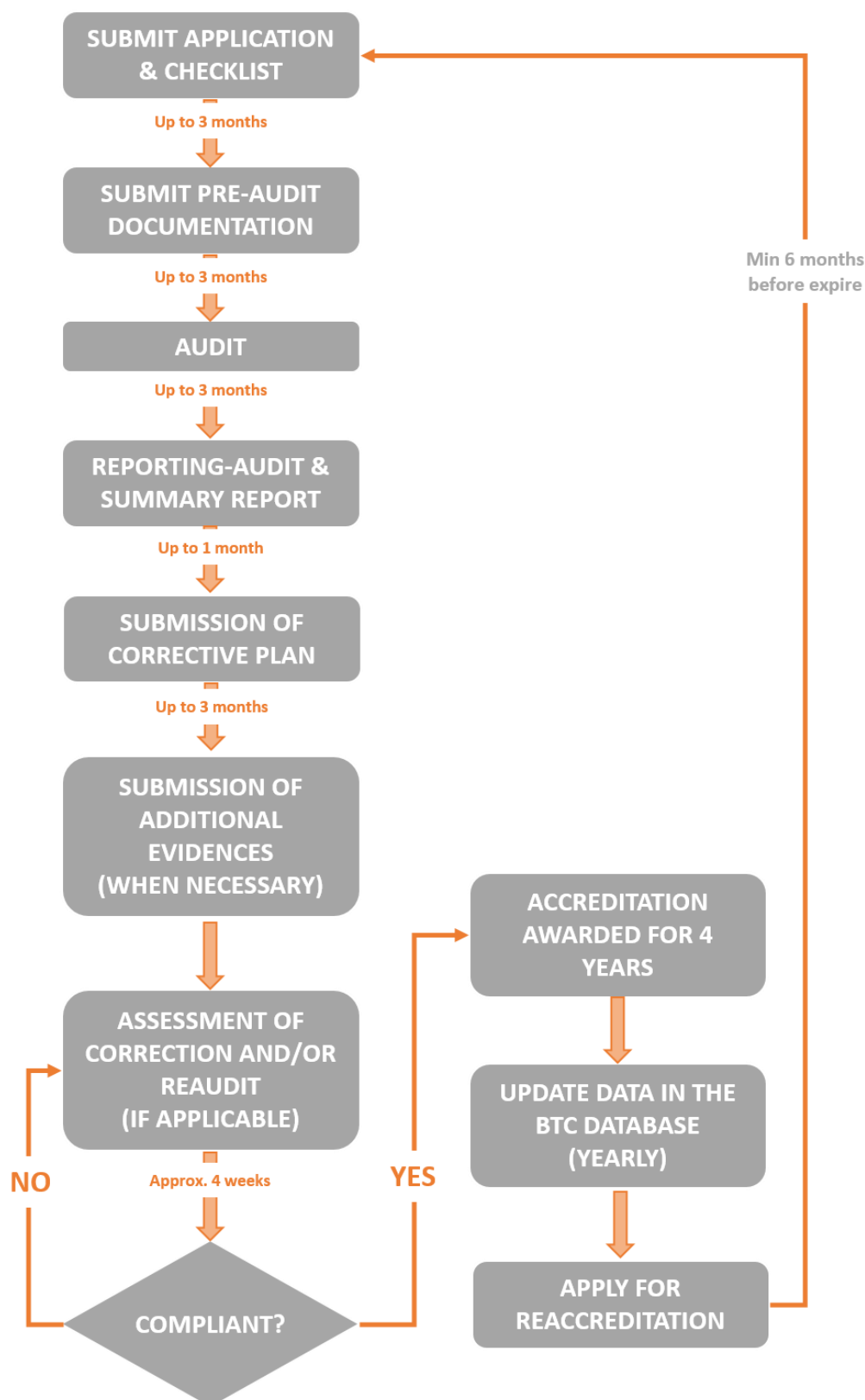
The EGALiTE approach to using volunteer subject matter experts is considered to be vital to the SoHO stakeholders accepting and embracing the accreditation process, as the auditors are part of the community and peers of the professionals working within the centres. This aims also to allow SoHO Entities to use EGALiTE to train their professionals on the best practice within the SoHO fields of activities, thus promoting the harmonisation and standardization of practices.

This guide is intended to be a ready reference for auditors to guide them through the tasks and responsibilities throughout all stages of an EGALiTE Accreditation.

The EGALiTE accreditation phases are summarised below (Figure 1.) and the detail of the auditor's responsibilities are described in the relevant sections that follow. For more information about EGALiTE Accreditation please visit the [EGALiTE website](#) and read the [Accreditation Guide](#).

<sup>1</sup> Auditor Handbook. JACIE. <https://www.ebmt.org/> (Acceded October 2023)

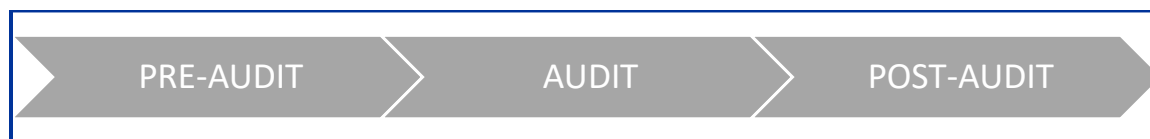
<sup>2</sup> *Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy: The JACIE Guide*. Mahmoud Aljurf, John A. Snowden, Patrick Hayden, Kim H. Orchard, Eoin McGrath. ISBN 978-3-030-64491-8 ISBN 978-3-030-64492-5 (eBook) <https://doi.org/10.1007/978-3-030-64492-5>



**Fig.1 – Representation of the EGALITE’s accreditation process**

# Accreditation Process

The EGALiTE accreditation process consists of three phases and there are important processes within each phase that auditors are involved in (Figure 2).



**Fig.2:** The three phases of the EGALiTE accreditation process

## Pre-Audit

This phase covers all activities from the time a SoHO entity submits an accreditation application to the EGALiTE Coalition until the date of the audit. The first activity is for the SoHO entity to apply to the EGALiTE Coalition and identify the activities, team(s), facilities, etc., setting out the scope of the activities which will be accredited. This task can be achieved by using the application form/EGALiTE accreditation Platform.

Then comes the signing of an accreditation agreement and submission and review of the pre-audit documentation. These tasks are managed by the EGALiTE Coalition, using the EGALiTE accreditation Platform.

## The role of the auditor during the pre-audit

Auditors will liaise closely with the accreditations' coordinator in the pre-audit phase to ensure that they work collaboratively with their auditor colleague(s) to prepare and plan for the audit.

Each auditor shall have completed an EGALiTE training course for new auditor, passed the associated exam based on the EGALiTE Standards and complete periodic auditors training modules as prepared by EGALiTE.

## The Audit Team

The audit teams typically include an auditor from each area included in the scope and an auditor for the Generic SoHO Standards. The final number of auditors will depend on the number of sites within the defined scope, and whether the audit includes different SoHO. One auditor will also be assigned the role of team liaison. If needed, observers/trainees and/ or language facilitators can be included in the team.

## Putting the team together

The assignment of auditors is carried out by the EGALiTE Coalition, following pre-defined criteria outlined in the document '[Auditor Job Description](#).' When the SoHO entity is ready for audit (i.e. required information and associated documentation correctly uploaded in the Accreditation Platform), the EGALiTE Coalition will contact

the auditors according to the mentioned criteria and auditor's availability.

When a team has been formed, the EGALITE Coalition liaises with everyone to agree on dates, book dates in the diary and await final confirmation from the EGALITE Coalition. It is essential that potential auditors alert the EGALITE Coalition to any potential conflicts of interest including, but not limited to the ones listed below (see Table 1). The EGALITE Coalition will decide if the potential conflict of interest is sufficient to exclude them from the audit. Transparency is key to the EGALITE culture and an important part of ensuring the consistency and impartiality of the audit process.

| <b>Table 1: Conflict of interest scenarios and actions</b>                                                |                                                           |
|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>SCENARIO</b>                                                                                           | <b>ACTION</b>                                             |
| Auditor is or has been an employee of centre that has applied for EGALITE Accreditation                   | Auditor shall not participate in the audit of the centre. |
| Auditor participated in the previous audit of a centre that has applied for EGALITE Accreditation.        |                                                           |
| Family members of the auditor are part of the staff at the centre going through the EGALITE Accreditation |                                                           |
| Auditor has a personal relation with the centre.                                                          |                                                           |
| Auditor has directly assisted centre with audit preparations                                              |                                                           |

The EGALITE Coalition understands that most auditors will require authorisation from their employers to participate in an audit and this might take a little time, however it is very helpful to get a prompt response about the auditor's intentions i.e., they are unable to participate or are seeking approval from their employer.

## Preparing for an Audit

During the pre-audit phase, centres share the pre-audit documentation, submitting the information in the EGALITE Accreditation Platform. Auditors will be given access to this platform before the audit.

## What is the EGALITE Accreditation Platform

EGALITE Accreditation Platform is the tool EGALITE uses as a secure place to store, organise, share, and access information submitted by the applicants. This tool includes many other features that aim to simplify the processes performed by auditors, applicants and members of EGALITE Coalition.

Auditors need a web browser (such as Microsoft Edge, Internet Explorer, Chrome, or Firefox) and credentials to access the Platform. Credentials will be disclosed by the EGALITE Coalition, to designated and accredited EGALITE Auditors.

Auditors should work collaboratively in the EGALiTE Accreditation Platform rather than downloading files. This is to ensure that the most up to date version of all information related with the auditor's assessment, is always available to the whole audit team.

## How to Access the EGALiTE Accreditation Platform

EGALiTE Coalition notifies the auditors what USERNAME and PASSWORD to use to log in to the Accreditation Platform.

Auditors must sign a Non-Disclosure Agreement and should not share their credentials with others.

## Review of pre-audit information and documents

Pre-audit documents/information include the checklist and other supporting documentation (see text box below).

As English is the official EGALiTE language, there is a minimum set of information, requested in the Accreditation Platform, which shall be submitted in English. However, EGALiTE will make its best efforts to assign auditors with knowledge in the same language as the applicant. In these situations, the supporting documents will be in the language of the centre, but if necessary, the centre can be asked to translate them into English (revised automatic translations, namely using the free eTranslation neural machine translation service provided by the European Commission, are accepted for simple documents).

When centres submit their pre-audit documentation, the EGALiTE Coalition reviews its completeness, but it does not review the content. Auditors should review pre-audit documentation before the audit so that they are prepared in advance. If auditors want to review additional documentation before the audit, they may use the Accreditation Platform to perform this step.

The auditor can also request extra supporting documentation during the audit. When reviewing the pre-audit documentation, auditors can already start completing the assessment of the checklist, particularly those standards that can be reviewed based on documentary evidence. Ideally, auditors will have reviewed the pre-audit documentation two weeks before the audit.

Pre-audit assessments (including the evaluation of self-assessment checklist) will be duly registered in the accreditation platform.

|                                            |                                                                             |
|--------------------------------------------|-----------------------------------------------------------------------------|
| – Specific SOPs                            | – Activity reports                                                          |
| – References to specific existing document | – Template of consent forms.                                                |
| – Licenses and authorizations              | – Sample labels                                                             |
| – QM Manual (or equivalent)                | – Facility Plans                                                            |
| – Biovigilance Data                        | – List of critical suppliers and/or third party agreements (when requested) |

Supporting documents submitted by the centre in the Accreditation Platform.

## Self-Assessment Checklist

The self-assessment is included in the features of the Accreditation Platform and is a source of information and evidence to the audit team, and the EGALiTE Coalition. It is a self-assessment against the standards and the centre must indicate whether they are compliant or not.

## Distribution of the standards

The self-assessment for the 1<sup>st</sup> edition of EGALiTE standards is divided into the following sections and auditors will be responsible for the sections in the assessment depending on their area of expertise:

|                                       |                                    |                        |                                                  |
|---------------------------------------|------------------------------------|------------------------|--------------------------------------------------|
| GENERIC STANDARDS FOR SoHO ACTIVITIES | A. DONOR SELECTION & DONATION:     | A.1. LIVING DONATION   | F. OCULAR TISSUES                                |
|                                       |                                    | A.2. DECEASED DONATION | G. AMNIOTIC MEMBRANE                             |
|                                       | B. COLLECTION/PROCUREMENT          |                        | H. SKIN                                          |
|                                       | C. PROCESSING, STORAGE AND RELEASE |                        | I. CARDIOVASCULAR TISSUES                        |
|                                       | D. DISTRIBUTION                    |                        | J. MUSCULOSKELETAL TISSUES                       |
|                                       | E. REGISTRIES AND VIGILANCE        |                        | K. UMBILICAL CORD BLOOD                          |
|                                       |                                    |                        | L. ADIPOSE TISSUE                                |
|                                       |                                    |                        | M. HUMAN MILK                                    |
|                                       |                                    |                        | N. BLOOD COMPONENTS FOR TOPICAL USE OR INJECTION |
|                                       |                                    |                        | O. INTESTINAL MICROBIOTA                         |

Some sections will not be relevant to the application and will not be part of the checklist the audit team visualizes in the Accreditation Platform.

## Auditor responsibility

Certain sections of the EGALiTE standards, can be assessed by different auditors (namely standards applicable to different activities and specific SoHO). It is therefore important to define who will assess each section to avoid an incomplete audit and checklist. The audit's team liaison has a special role in the attribution of these responsibilities.

The communication tools available in the EGALiTE Accreditation Platform provides assistance for these assignments.

## Audit organization

### Audit Plan

Team liaisons are ultimately responsible for preparing the audit agenda / plan from a template provided by the EGALiTE Accreditation Platform.

Team liaisons will coordinate with the other members of the audit team to agree on the timetable and list of staff to interview during the audit. Auditors will base the interview plan on the organigram (included in the pre-audit documentation) provided by the applicant. It is the responsibility of all auditors to contribute to the audit plan for their area/scope to ensure that the centre and its personnel are available on the day and the auditors can make the most of their time.

It is important that auditors issue the audit agenda/plan at least two weeks before the audit. Once the agenda is completed by the auditors, the EGALiTE Coalition must be notified using the EGALiTE Accreditation Platform.

The EGALiTE Coalition will forward it to the applicant. The centre will add information about the location and names of the personal that need to be interviewed.

Once confirmed, the agenda is sent back and shared with auditors and applicant, using the EGALiTE Accreditation platform.

Below is an **example** of agenda for the onsite audit. In any case, the Audit Plan's aim is to assist auditors and applicants, changes in the Audit Plan may be possible and needed, in order to adjust to Applicants availability, or other constraints.

| TIME                            | LOCATION<br>To be completed by<br>APPLICANT | ACTIVITY                                                      | AUDITORS | ACCOMPANYING STAFF<br>To be completed by<br>APPLICANT |
|---------------------------------|---------------------------------------------|---------------------------------------------------------------|----------|-------------------------------------------------------|
| 08:00-08:30                     |                                             | Meet audit team and accompany them to meeting room            |          |                                                       |
| 09:00-09:30 approx.<br>30-60min |                                             | Opening Meeting                                               |          |                                                       |
| 09:30-10:30 approx.<br>30-60min |                                             | Tour around facilities demonstrating links between facilities |          |                                                       |
| 10:30-12:00 approx.<br>30-60min |                                             | Document review                                               |          | QM to be available during the review of documentation |
| 12:00-13:00                     |                                             | WORKING LUNCH                                                 |          |                                                       |
| 13:00-16:00                     |                                             | Document review and interviews                                |          | QM to be available during the review of documentation |
| 16:00- 16:30                    |                                             | Audit team meeting                                            |          |                                                       |
| 16:30- 17:30                    |                                             | Closing meeting                                               |          |                                                       |

## Travel arrangements

EGALiTE recognizes the considerable effort made by auditors when performing site visits. Therefore, to ease the burden, travel arrangements and trips are booked directly by the travel agency named by the EGALiTE Coalition. Once the audit has been confirmed, auditors will be contacted by the travel agency by email. Auditors should communicate their preferences to the travel agency as soon as they are contacted as a delay means there will be less options available. If they do not receive an email from the travel agency, they should let the EGALiTE Coalition know. If changes (including cancellations) to the reservations are necessary, the auditor must contact the travel agency directly by email or by phone.



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Auditors are responsible for obtaining any entry VISA, if needed. Auditors are responsible for any necessary vaccination when travelling to countries where compulsory immunisation is required for travel or to enter the territory. EGALITE will reimburse any cost related to vaccinations and VISAs. Auditors should not book their own travel, as the travel agency can arrange trains and planes directly. The only exception is when travelling with their personal car and auditors can then claim the mileage.

## *Per diem payments*

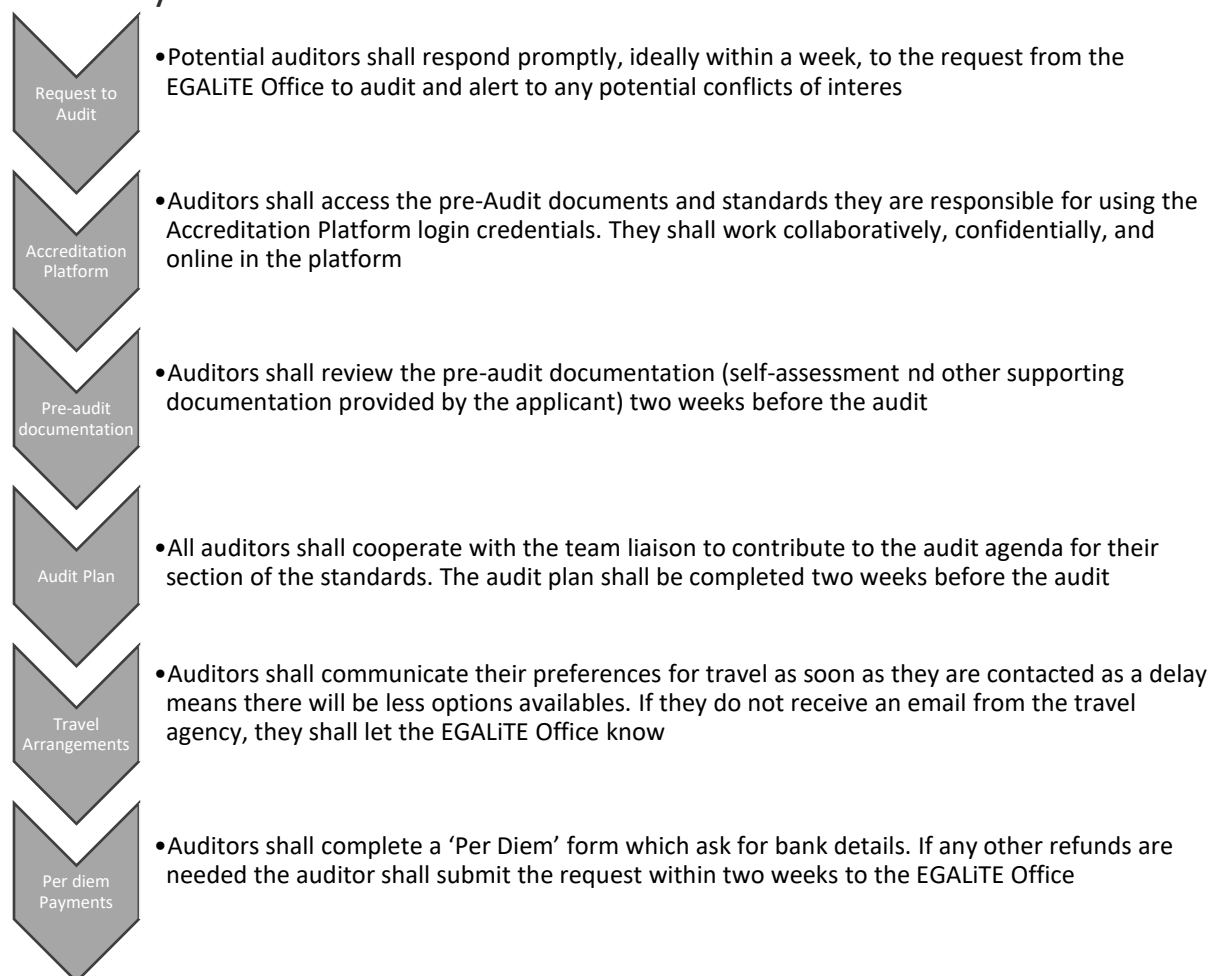
Auditors and trainees participating in onsite audits should not be out of pocket and EGALITE provides a daily allowance to cover expenses. The total amount depends on the duration of the audit. For example, three days are usually awarded for a two-day audit to take into consideration travel and preparation. If any other refunds are needed the auditor should submit the request within 2 weeks after the end of the audit.

If auditors are participating in their first EGALiTE audit, the EGALiTE Coalition will ask that they complete a 'Per Diem' form which will ask for the bank details. If a returning auditor, it is essential that the EGALiTE Coalition is informed if the bank details have changed since the last audit.

The amounts of per diem were determined based on the reference subsistence values determined by the EC commission for the different countries. The reference values are available [here](#).



## Summary



## Audit

Usually, the duration of on-site audits is estimated to 1.5 days (but this can vary depending on the complexity of the scope of accreditation).

The audit team should be given a separate room to use as a base to ensure privacy.

## Format of the opening meeting

### *Applicant:*

During the opening meeting, the applicant presents the activities performed by the centre and describes the structure of the organisation, location of sites, presents any information that may be helpful to the team, particularly items not included on the self-assessment or required documents list.

### *Team liaison:*

The team liaison introduces the audit team and explains the purpose of the audit and working methodology. The team liaison will explain that auditors are the eyes and ears of the EGALiTE Coalition and that they do not make the final decision as to whether accreditation is awarded. The audit agenda/plan is confirmed, and the applicant is reassured that the information obtained during the audit is strictly confidential.

## Format of closing meeting

Three meetings are held to bring the audit to a close:

### *Audit team meeting*

Only the members of the audit team attend and it is a time to discuss and compare findings within the team. This is a good time to start completing the report and ensure all the parts were audited and share the information between the auditors.

### *Exit meeting with the Responsible Person (when applicable)*

This is usually conducted between the team liaison and the Responsible Person, **when any sensitive issues arise from the audit**. Other members of the audit team can be invited and should also be prepared to discuss findings with the Responsible Person.

### *Closing meeting*

This meeting closes the audit and is led by the team liaison, with the support of all auditors. It is attended by the full audit team, the Responsible Person, medical directors, and anyone who accompanied the audit team during the audit; supervisors; and any other facility personnel invited by the Responsible Person.

This is a time to thank the departments involved and to present the main findings of the audit so there are no surprises when they receive the final report. It is recommended to indicate first the areas for improvement and then the centre's strong points. Finishing with the best part can leave a better impression with centres. Centres should be able to start addressing the deficiencies based on the closing meeting.

### *Important notes for Auditors:*

- Avoid making promises or speculations: Auditors may provide an indication if the audit has proceeded positively; however, they should refrain from making references to the final outcome, as the ultimate decision is made by the EGALiTE Coalition.

- Explain that you will report your observations; these are reviewed by all the auditors participating and then summarised for presentation to the EGALITE Coalition. The EGALITE Coalition makes the final decision on accreditation.
- If you do not know the answer to a question, say so. Notify the EGALITE Coalition immediately if there are unanswered questions from the applicant that require answers before a final report is available. You should include applicant questions in your report.

## Post-Audit

### Feedback through online survey

Once the audit is completed, the applicant and the audit team will receive an audit evaluation form. It is important that this form is submitted within 2 weeks.

The form should be used to formally state satisfaction or to raise any issues that may have occurred during the audit. It also gives the applicant an opportunity to give feedback on the process overall, identify strengths and areas for improvement.

The evaluation by the centre will also be sent to the auditors for their information and response where necessary.

### Audit report

The Audit Report has two parts:

1. The Audit Summary which includes the basic information about the centre, the programme structure, team liaison summary and overall impression of the audit. Data, numbers, and the names of staff reflected in the Application Form may be outdated by the time auditors are completing the audit report. It is important that auditors ask for the latest information during the audit.
2. The completed assessment checklist that includes the specific observations on each of the individual items in the checklist. The auditors need to complete and submit the final Audit Report in the Accreditation Platform, within 2 weeks of the audit. The report is the fundamental part of the process, and all the decisions are based on the information presented within it.

## How to complete the audit summary and checklist

### *Audit Summary*

All auditors should complete the report sections related with the sections they visited.

The following must be included in the Audit Summary:

- ✓ Overall activities: Number of procedures (donations, collections, preparation processes, units distributed, etc.) based on the scope of the activities included in the accreditation

- ✓ The facilities visited
- ✓ The names of the directors of the service(s) visited
- ✓ A brief description of the programme or facility e.g., years functioning, main activities, relationship with other services or SoHO Entities
- ✓ A description of the services provided to other facilities not visited during the audit including donor registries, collection sites, testing labs, etc.
- ✓ A comment on the interactions between the different organizations involved in the SoHO chain
- ✓ An indication of the distance between relevant sites with activities with impact for the quality and safety of SoHO
- ✓ Any additional information considered relevant to the report
- ✓ Any comments on the documentation received and reviewed prior to the on-site visit

## Self-Assessment Checklist

The Self-Assessment checklist is first completed by the applicant in the Accreditation Platform and then validated by the auditors.

### *Assessment of compliance*

Auditors can assess the compliance of standards as follows:

- **Compliant** – all aspects of the standard are met
- **Partially compliant** – some, but not all aspects are met.
- **Non-compliant** – none of the aspects are met.
- **Not applicable** - where the standard is not applicable to the specific activity/SoHO in the applicant facility or programme. (NOTE: this should not be used for something that is not compliant).

There are situations where an auditor will find differently to an applicant and change the compliance on the checklist. In these instances, the auditor **must always provide a clear supporting comment**.

## Applicability of standards

The EGALITE standards cover the SoHO activities from donor selection to SoHO distribution. Depending on the accreditation goals, a certain set of EGALITE standards apply.

If an Auditor has stated that a standard or set of standards is not applicable, a reason must be given to ensure that the EGALITE Coalition is aware of the centre's way of working and that 'not applicable' has been correctly selected. Another one, which is sometimes tricky, is in the case where the applicant has assessed a standard as 'not applicable'. The Auditor should stand back and assess if the standard 'could' be applicable in certain circumstances and assess whether the centre would be compliant if the situation were to arise.

Auditors must take care to ensure that they assess all the standards that are applicable to a centre.

## EGALITE process after Audit

The Audit report is initially reviewed by the EGALITE Coalition to ensure that all standards have been assessed and are consistent across the different sections, where appropriate. The report is then reviewed by the EGALITE Coalition. The EGALITE Coalition will decide/confirm on the level of compliance against the standards based on the information provided in the report by the auditors and set the time given to the centre to correct any deficiencies.

Subsequently, the EGALITE Coalition report and annotated checklist are sent back to the Applicant who must provide evidence of correction of any deficiencies within the allocated time period. This evidence is then reviewed by the initial audit team and once they consider that all the deficiencies have been corrected, the final report will be approved by the EGALITE Coalition and the Applicant will be notified of its accreditation.

When necessary, a follow-up of the EGALITE's Technical Assistance Programme (TAP) will be recommended to the applicant, to assist with the correct implementation of corrective measures.

## Variables affecting the reporting process

### *Not fully completed reports*

If an applicant and auditor have found a standard not applicable, a reason must be given.

If an applicant and auditor have assessed the compliance of a standard differently, a reason must be given.

### *Inconsistencies*

It is important that information provided by the auditors in the summary report and/or checklist is consistent with the information in the application form. If the information is different, a reason must be provided so that the EGALITE Coalition does not have to refer a report back to the auditors for clarification.

Another point is that there must be consistency across standards. As some general quality standards are applicable across different sections of the standards, it is important that the auditor responsible for the assessment of Generic SoHO requirements, takes some time when they have completed the checklist to do a cross-check across the standards to ensure they have consistently reported the same findings where appropriate.

It is also good practice for the Team Liaison to check that all standards have been assessed by the individual auditors and for some standards where e.g., the collection auditor and the generic SoHO requirements auditor are reviewing similar standards e.g., training, supplies management, equipment management; that the respective assessment in each section is consistent. As an example, a collection auditor might review the storage of the collected SoHO while the Generic SoHO requirements Auditor might look at the standard operating policies for these areas. The assessment of these affiliated standards should be similar between auditors.

The information provided by the auditors in the summary report and checklist must also be consistent so that the EGALITE Coalition does not have to refer a report back to the auditors for clarification.

Standards are not applicable if they are not mandatory, and the centre does not include them in the service (Example: When a center does not perform living donation, the standard related to this activity does not apply).

EGALiTE standards must be followed if they are more stringent than the local / national regulations.

Please remember that the EGALiTE Coalition checks if all topics are covered but does not have access to the documents (i.e. only verifies the completeness of the submission in the Accreditation Platform, not the content of the documents uploaded), does not interview staff and does not visit the centre and therefore, the auditors must explain why they have assessed the compliance of the standards as they have.

## *Interpretation of standards*

Standards are compliant if the centre provides evidence as stated in the manual. Standards must be evaluated against the criteria outlined in the standard and cannot be found non-compliant or partially compliant if they have provided evidence that they meet the requirements (example of this below).

## *Self-Assessment Checklist summary:*

Auditors should:

- DO add a comment if your assessment is anything but compliant, so that the EGALiTE Coalition and the centre understands your assessment.
- DO add a comment if you change the centre's self-assessment.
- DON'T add a comment for standards that you and the centre have assessed as compliant.
- DO assess every standard.

The completion of the report should start before the audit. It is important to start drafting the checklist with notes about what standards need more focus before the audit and during the review of the pre-audit documentation.

During the audit, make sure that all is reviewed and note down observations, fill in the checklist and report as much as possible.

Auditors should never make a standard non-compliant because they did not have time to assess it during the audit. Auditors must manage the time so that they can assess all the standards.

Auditors should not add questions or question marks to their comments in the checklist. If there are doubts or remaining questions during the audit, the Auditor must mark that standard as non-compliant or partially compliant and highlight in the comments what further information is needed in order to assess the standard. The EGALiTE Coalition does not assess standards, and Auditors must ensure they have enough information from the centre or set out what is missing and why the standard is not compliant. Auditors are responsible to assess the standards and resolve issues related to them.

A good practice is to do a recap at the end of the day and cross-reference the checklist and identify what is done and what still needs to be completed.

At the end of an Audit, share conclusions with the Audit team to ensure consistency.

## Recommendations for improving the report process

- Complete the report as soon as possible after the Audit. A delay in preparing the report has a detrimental impact on the quality of the report and on the audit process.
- It is highly recommended to draft the audit report (introduce the information in the Accreditation Platform) while still onsite. It is easier to remember key points and will ensure this task is completed outside of your normal work.
- The checklist is an important document which is reviewed by the EGALiTE Coalition. If a standard has been assessed differently by the centre and auditor, a comment **must** be included so that the auditor's finding is clear. For example, if a centre has marked a standard compliant, but the auditor has found it rather non-compliant, then a reason must be noted in the comment section.
- Checklists, along with the audit report, must be completed in Accreditation Platform at the end of the Audit. If this is not possible, auditors should aim to submit their reports within 2 weeks of the audit.
- Auditors are also required to assist with later phases of the audit process. Once the centre has submitted evidence that they have corrected the deficiencies, auditors must review this evidence.
- Although highly unlikely, auditors may be needed to conduct a second audit of the centre if major deficiencies were found.

## EGALiTE process after audit

The audit report is initially reviewed by the audit team to ensure that all standards have been assessed and are consistent across the different sections, where appropriate. The audit team will decide on the level of compliance against the standards based on the information gathered by the auditors and set the time given to the centre to correct any deficiencies. Subsequently, the report validated by the EGALiTE Coalition and annotated checklist are sent back to the Applicant, who must provide evidence of correction of any deficiencies within the allocated time period. This evidence is then reviewed by the initial Audit team and once it considers that all the deficiencies have been corrected, the final report will be approved by the EGALiTE Coalition and the SoHO Entity will be notified of its accreditation.

It is, however, important to highlight that, due to the potential impact of major and critical non-compliances, shorter timeframes may be defined to correct deficiencies found during the audit. For example, auditors may agree with the applicant the immediate implementation of urgent corrections after the audit, in order to facilitate the progression of the accreditation process.

## Accreditation timeframe

The accreditation is valid for four years following an on-site audit (commencing from the date that accreditation is awarded), after which the centre is required to reapply to maintain accreditation. It is important to note that, unlike many Competent Authorities' processes, the EGALiTE accreditation process involves volunteer auditors who have other commitments, and this is reflected in the time to completion of some of the EGALiTE accreditation process steps. As the pre-audit stage can take up to six months (up to 3 months for submitting

application and self-assessment and up to three months to submit the pre-audit documentation), and the EGALITE Coalition can allocate up to three months to address the deficiencies identified by the audit team, it is possible that the end-to-end accreditation process to take 12 months.

## How to deal with unexpected events

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### Auditor illness or Travel Upheaval

In the unfortunate situation that an auditor is unexpectedly unable to participate in an audit, it is important the EGALITE Coalition is notified as soon as possible so that appropriate steps can be taken to mitigate this.

## Frequently asked questions

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### *When is the Audit happening?*

Auditors receive an invitation to take part in an audit and dates are arranged once the team is complete. Dates are aligned with everyone's availability. Therefore, it is essential that potential auditors respond promptly, to the request to inspect and alert the EGALITE Coalition to any potential conflicts of interest.

### *What if I do not have time to review all the standards in the checklist?*

It is important that you manage your time well during the audit. A good tip is to review the checklist at the end of the first half day, also at the end of second half day, and in the middle of the third half day. Speak to your auditor colleagues if you have queries as they might have observed the area you have questions about. You cannot assess a standard as partially or non-compliant because you have not reviewed it. Therefore, review as much as possible before the audit and keep on top of time management during the audit.

### *What if I do not know if a standard is compliant or not?*

Ask the other Auditors for help, particularly the team liaison. They may have seen something related to that standard that will help you with your assessment. If it is a particular issue related to the centre, you can query the matter with the EGALITE Coalition. In these cases, inform the centre that a further review by the team must be done, and that the final decision will be in the report.

### *Can I request printed copies of the standards or manual?*

EGALITE does not provide printed copies of the Standards or Manual. You can of course download and print a copy yourself.

### *Should the centre collect auditors from hotels/ airports?*

No, this is not necessary. If the hotel is close to the centre, someone from the centre can pick the auditors up from the hotel lobby and guide them towards the facilities to be inspected. However, this is not a requirement and auditors can get the information about the best route from the hotel to the facilities (e.g., taxi, walking or bus) in advance of the audit.

## *Should the key personnel from the centre join the auditors for meals during the Audit dates?*

No, the centre is required to arrange a modest business lunch for the auditors. Considering that time is limited during the audit, auditors may want to consider this a working lunch and will usually use the time to go over notes and discuss them with the rest of their team.



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## Auditor's Job Description (Document 5)

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# EGALiTE – Auditor’s Job Description

## Accreditation Dossier (Document 5)

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EUROPEAN GROUP FOR ACCREDITATION AND  
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

|                      |                               |
|----------------------|-------------------------------|
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| Work package:        | WP5 – Accreditation Programme |
| Author(s):           | WP5 Working Group             |
| Dissemination level: | Public                        |



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This guidance document has been defined based on the contents and defined in the Job Description JACIE Inspectors<sup>1</sup>.

## Mission

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As an expert in their field(s) of the Substances of Human Origin (SoHO), auditors evaluate compliance of the applicants with the EGALiTE standards in the interest of continuous improvement of the quality and safety of SoHO.

## Responsibilities and Tasks

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### A) Pre-Audit

- **Prepare the Audit:** Carefully review all the pre-audit documentation submitted by the applicant & Self-Assessment Checklist. Identify where auditors have doubts or questions to check deeper during the audit.
- Actively participate in the pre-audit teleconference: the team liaison will organize it and lead it, and make sure that all the auditors understand their role and the scope of the audit. Clarify who is doing what to avoid overlapping, and other practical aspects.
- Ask for more documents or clarifications to EGALiTE's office/using the Accreditation Platform during the pre-audit phase, if applicable.
- Maintain the confidentiality of information that is accessed in the course of work undertaken

### B) Audit

- Actively participate in the opening meeting. Adopt an approach of openness and transparency.
- Assessment of facilities and documents. Observe with impartiality, integrity and objectivity in relation to advice and activities that are undertaken.
- Interviews to the staff
- Meet privately with SoHO Entity's Responsible Persons or/and Director(s) as needed, particularly if auditors believe there are potentially significant problems. The message should be constructive (EGALiTE will give them support to achieve compliance with the standards).
- Closing meeting (summarize the major findings in the area audited, next steps, thank and cheer them up, encourage them in a positive way to keep working hard, promote continuous improvement)
- Fill in audit report and checklist and prepare of the Summary report (highly recommended when things are recent and fresh)

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<sup>1</sup> JOB DESCRIPTION JACIE INSPECTORS. JACIE Office. Effective date: 28/04/2021; Document Reference: JD Inspectors (<https://www.ebmt.org/sites/default/files/2021-05/JACIE%20Inspector%20-%20Job%20description.pdf>)

- Maintain the confidentiality of information that is accessed in the course of work undertaken

## C) Post Audit

- Submit to Audit Team Liaison the auditor's inputs for the report in the Accreditation Platform (s/he will verify all contribution and validate them to send it to EGALITE Coalition)
- Clarify any doubts (from EGALITE Coalition)
- Check the implementation of corrective action(s) (once the applicant corrects all deficiencies).
- Maintain the confidentiality of information that is accessed in the course of work undertaken.

## Summary of Audit Team roles Pre-Audit, during Audit and Post Audit:

| Tasks                                    | Team Liaison                                                                                                                 | Auditor                                                                        | Other<br>(Observer / Trainee) | Translator/ Facilitator                                                                                        |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------|----------------------------------------------------------------------------------------------------------------|
| <b>Timetable</b>                         | Prepare and approve the timetable and audit plan                                                                             | Comments and approval of the timetable                                         |                               |                                                                                                                |
| <b>Pre-audit documentation</b>           | Make sure the self-assessment information is completed and allows the correct assessment during audit                        | Read and get familiarized with the information included in the self-assessment |                               | Provide /assist the preparation of accurate information                                                        |
| <b>Pre-audit teleconference</b>          | Leads the teleconference call and makes sure that all the Audit team understands their role and the nature of the programme. | Actively participate in the teleconference                                     |                               |                                                                                                                |
| <b>Opening meeting</b>                   | Lead the Opening Meeting.                                                                                                    | Actively participate in the Opening meeting.                                   |                               | Observe the opening meeting and translation support, if needed.                                                |
| <b>Audit</b>                             | Audit the facilities that they are qualified for.                                                                            | Audit the facilities that they are qualified for.                              |                               | Observe the audit but without taking part in it. Only language support.                                        |
| <b>Interviews</b>                        | Interview the personnel of the facilities that they are qualified for.                                                       | Interview the personnel of the facilities that they are qualified for.         |                               | Verbal translation and language support to the audit team and personnel in order to ensure good communication. |
| <b>Closing Meeting</b>                   | Lead the closing meeting.                                                                                                    | Actively participate in the closing meeting.                                   |                               | Observe the closure meeting and verbal translation support, if needed.                                         |
| <b>Completion of the Audit Checklist</b> | Complete their section of the Audit Checklist.                                                                               | Complete their section of the Audit Checklist.                                 |                               |                                                                                                                |

|                                                       |                                                                                                   |                                                                                                        |  |  |
|-------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--|--|
| <b>Completion of the Summary Report</b>               | Complete their audit part and the part of the team leader of the Summary Report.                  | Complete their audit part of the Summary Report and inform the Team Liaison and the EGALiTE Backoffice |  |  |
| <b>Finalize Summary Report &amp; Audit Checklist.</b> | Review the Summary Report and Checklist and inform the EGALiTE Backoffice that has been completed |                                                                                                        |  |  |

## Working conditions

Auditors are volunteers, these are some of the advantages of joining our team of auditors:

- An excellent way of learning about EGALiTE standards for auditor's own organization
- The opportunity to visit other SoHO Entities and see how other professionals work and organize themselves. Maybe auditors will get some good ideas to improve things in their organisation.
- Learn, sharing knowledge. See other ways of solving problems / addressing challenges.
- Networking. Meet and collaborate with other colleagues
- Contribute to promote and implement quality in SoHO fields and therefore improve our ability to provide care for patients.

EGALiTE will pay for auditor's travel expenses: flights or other transport means needed, accommodation, 2 days inspection per diem and 1 travel day per diem if applicable (per diem The amount of per diem were determined based on the reference subsistence values determined by the EC commission for the different countries. The reference values are available here). It is the Applicant the one in charge of hotel booking and of providing catering while auditors are on-site.

You are asked to commit to participating in 1 audit per year. In any case, audits are scheduled according to auditors' availability, so participation is never imposed.

Auditors could be asked to participate in audits in other countries where they speak the local language.

## Technical Requirements and Experience

The auditor shall hold a professional degree in medical and/or biological sciences, and five years' experience as a Responsible Person, Medical Director, or Supervisor of a SoHO entity's activities. Other roles may be accepted when a letter from the Responsible Person of their organisation confirms his/her experience in the relevant SoHO activities.

Being an auditor requires sufficient expertise in the subject matter to be able to identify potential issues.

Each auditor shall have completed an EGALiTE training course for new auditors, passed the associated exam based on the EGALiTE Standards and complete periodic auditors training modules as prepared by EGALiTE.

The auditor shall complete and sign confidentiality agreement and a statement to the effect that she/he is qualified by scientific training and experience to be an EGALiTE auditor.

Auditors collaborating with the EGALiTE Accreditation Programme shall sign Non-Disclosure Agreements (NDAs) and are obligated to maintain confidentiality regarding all information assessed during the accreditation procedures.

## Competencies

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Candidates to be auditors should have the following core competencies:

- Open-minded approach to audits and standards
- Commitment to EGALiTE standards and processes (included deadlines)
- Good communication and inter-personal skills, diplomatic
- Team spirit

Other important competencies to work as an auditor are:

- Results and excellence oriented
- Attention to detail, thoroughness
- Time management
- Organization and planning
- Service orientation to the Applicant Entity
- Objectivity



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# Criteria for Auditors' Selection/Assignment

While assigning the auditors to assess the applications submitted for accreditation, the EGALiTE Coalition will consider the following criteria:

| Mandatory criteria:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Auditor has successfully completed EGALiTE certified training in the previous 4 years</li> <li>• Fluency in English</li> <li>• Experts should be active professionals or should have retired no longer than two years ago</li> <li>• Working in his/her field of expertise for more than five years</li> <li>• Current working position at a non-for-profit organization, or retired from one (for no longer than two years)</li> <li>• Auditor coming from organization that holds a valid Authorization as SoHO entity for the SoHO activity required by the applicant, with a significant number of procedures)</li> <li>• Absence of conflicts of interest, specifically, auditors should not have been involved in EGALiTE's Technical Assistance Programme actions aimed at preparing or assisting with audit/accreditation preparation.</li> <li>• An auditor cannot be a person who is currently employed by or has worked as an inspector for a Competent Authority within the past 5 years, particularly in the fields in which they were active</li> <li>• Availability</li> </ul> |
| Preferable criteria:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <ul style="list-style-type: none"> <li>• Reduced travel distance(s) to the Applicant's facilities</li> <li>• The auditors are members of EATCB, EEBA, or similar society or association</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

## Privacy Policy (Document 6)

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# EGALiTE – Privacy Policy

## Accreditation Dossier (Document 6)

EUROPEAN GROUP FOR ACCREDITATION AND  
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

|                      |                               |
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## Privacy Policy (to be included in the Application Form of the IT Accreditation Platform)

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“The Personal Data provided will be used for the purpose of management of the EGALiTE Accreditation process and processed according to the General Data Protection Regulation (GDPR 2016/679). The data will be stored in an electronic database property of EATCB and EEBA which will be allocated in the EEA (European Economic Area) or in countries that are provided with the same level of protection for privacy. Data Subjects have the right of access, rectification, erasure, restriction, portability, and objection to the processing of his or her personal data. If you wish to exercise any of the rights listed above, please write to [coordination@egalite-europe.eu](mailto:coordination@egalite-europe.eu). For further information please go to the Privacy Policy (<https://www.egalite-europe.eu/>)”.

## Privacy Policy (to be included in the EGALiTE website)

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“At the EGALiTE Accreditation Programme, we are committed to protecting your privacy and ensuring the security of your personal information. This Privacy Policy outlines how we collect, use, disclose, and safeguard your data in accordance with the European General Data Protection Regulation (GDPR).

### 1. Collection of Personal Information:

We collect personal information from Applicants. This information may include but is not limited to names, contact details, financial identification, organization affiliations, and professional qualifications.

### 2. Use of Personal Information:

We use the personal information collected for the purposes of administering the EGALiTE Accreditation Programme, communicating with Applicants and Auditors, providing support, and improving our services. Your information may also be used for statistical analysis and reporting, ensuring compliance with regulatory requirements, and fulfilling legal obligations.

### 3. Disclosure of Personal Information:

We do not disclose your information to third parties except where required by law, regulation, or legal process. In some cases, we may share data with trusted service providers who assist us in operating our Accreditation Platform, website, conducting our business (auditors), or servicing you, provided that they agree to keep this information confidential.

### 4. Security Measures:

We implement appropriate technical and organizational measures to protect your personal information from unauthorized access, disclosure, alteration, or destruction. However, no data transmission over the internet or method of electronic storage is 100% secure, and we cannot guarantee absolute security.

## 5. Your Rights:

Under the GDPR, you have the right to access, correct, update, or delete your personal information. You may also object to the processing of your data, request restrictions on processing, or withdraw your consent for future processing. To exercise these rights or inquire about our privacy practices, please contact us using the information provided below.

## 6. Changes to this Privacy Policy:

We reserve the right to update or modify this Privacy Policy at any time. Any changes will be posted on this page with a revised effective date. Your continued use of our website after any such modifications constitutes acceptance of the revised policy.

## 7. Contact Us:

If you have any questions, concerns, or requests regarding this Privacy Policy or the handling of your personal information, please contact us at [coordination@egalite-europe.eu](mailto:coordination@egalite-europe.eu).

Thank you for entrusting us with your personal information. We are committed to safeguarding your privacy and ensuring transparency in our data processing practices.”



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