



Standard operating procedure

Title: Renewal of SME status		
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1. Purpose

To describe the procedure for maintaining the SME status pursuant to Articles 2.1 and 4 of [Regulation \(EC\) No 2049/2005](#) of 15 December 2005, and Article 8 of [Regulation \(EU\) No 658/2014](#) of 15 May 2014.

2. Scope

This SOP applies to the SME Office (TRS-SME) within the Regulatory Science and Innovation Task Force (TRS), and the Legal Department (AF-LD) within the Advisory Functions (AF), if necessary.

3. Responsibilities

It is the responsibility of the Head of Service and Head of the Task Force to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

Updates to align with changes to EMA organisational structure, responsibilities, templates and records management.

5. Documents needed for this SOP

All templates can be found at: [X:\Templates\Others\SME\SME submissions](#)

- Template 1: Sign off sheet
- Template 2: Acknowledgment of receipt to applicant



- Template 3: Request for clarification
- Template 4: Reminder
- Template 5: Information of closure of SME file to applicant
- Template 8: Qualification of SME status – renewal regulatory consultancy or annexed to consultancy
- Template 9: Qualification of SME status – renewal

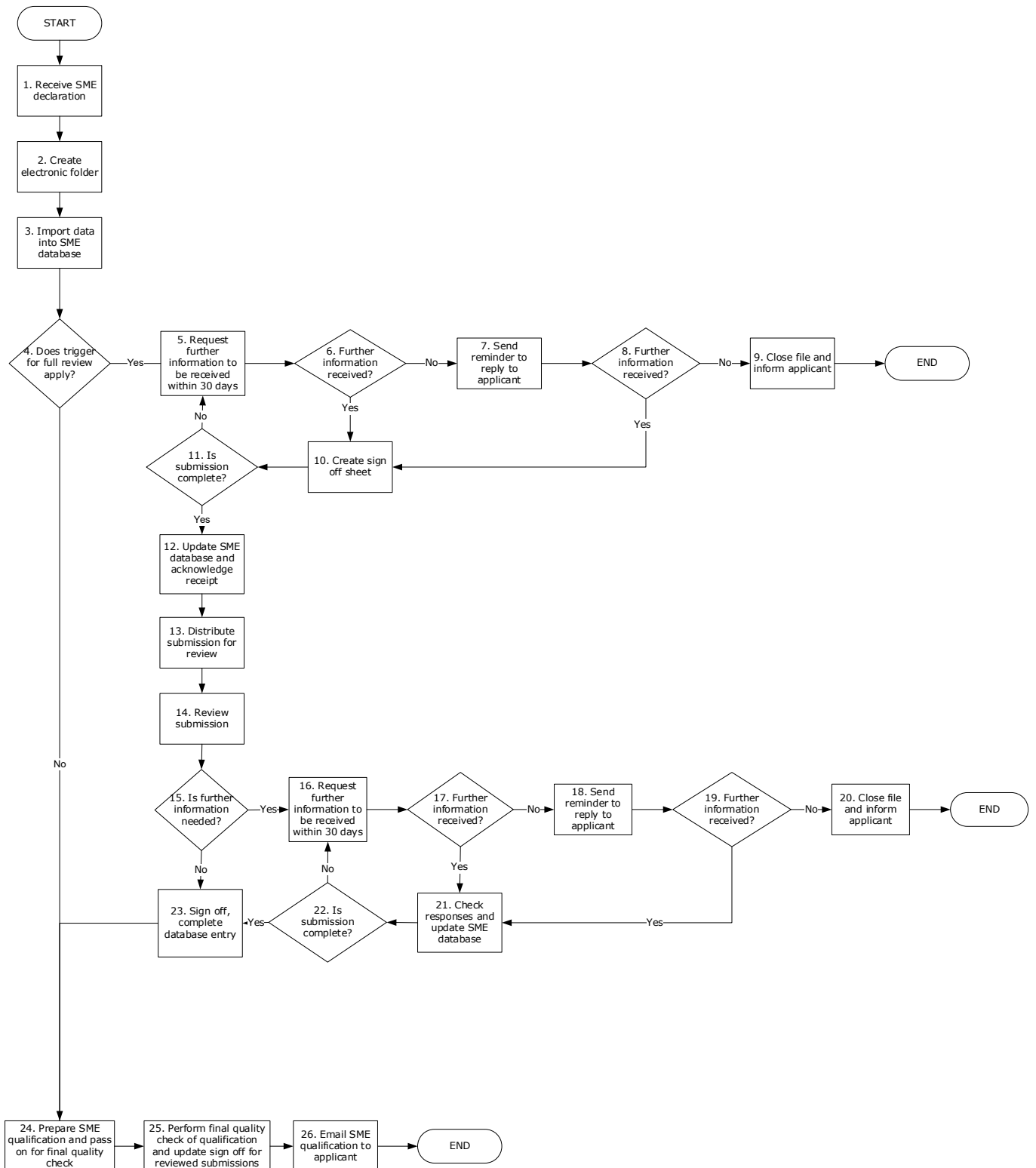
6. Related documents

- [Declaration on the qualification of an enterprise as a micro, small or medium-sized enterprise \(SME\)](#)
- [Regulation \(EC\) No 2049/2005](#)
- [Regulation \(EU\) No 658/2014](#)
- [SOP/EMA/0039 on Assignment of SME status](#)

7. Definitions

AD:	Administrator
AST:	Assistant
AF:	Advisory Function
AF-LD:	Advisory Function – Legal Department
DREAM:	Document records electronic archive management system
EC:	European Commission
EMA:	European Medicines Agency
HSer:	Head of Service
No:	Number
SAP:	Systems, Applications & Products in Data Processing
SME:	Small- and Medium-sized Enterprise
SOP:	Standard Operating Procedure
TRS:	Regulatory Science and Innovation Task Force
TRS-SME:	Regulatory Science and Innovation Task Force - SME Office

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
Submission of SME renewal declaration		
1	Receive SME declaration form electronically in XML format from applicant.	AST in TRS-SME
2	Create electronic folder for submission in DREAM.	AST in TRS-SME
3	Import data from XML file into SME database.	AST in TRS-SME
4	If one of the following triggers for full review applies, go to step 5: <ul style="list-style-type: none"> change in the type of the enterprise (autonomous, partner, linked) and/or amendments to annex A and/or B of the SME declaration form, resulting from significant changes in the upstream or downstream ownership structure. Examples of significant changes include: acquisition, takeover, merger of the applicant and its partner/linked entities; new acquisitions by the applicant and its partner/linked entities; major changes of shareholders capitalisation of the applicant and its partner/linked entities); SME thresholds exceeded over one accounting period; the company's previous submission was based on a bona fide estimate of the financial data; the company's SME status has expired and there is one or more years of accounting data missing since the last submission; <p>If none of the above applies and SME criteria are met, go to step 24.</p>	AST in TRS-SME
Request for supporting documentation		
5	Acknowledge receipt, request further information to be submitted within 30 days (template 2), including supporting documentation for address/company name changes (if applicable) and update SME database.	AST in TRS-SME
6	If further information is received, go to step 10. If further information is not received within 15 days, go to step 7.	AST in TRS-SME
7	Send reminder to reply to request for clarification (template 4) to applicant.	AST in TRS-SME
8	If further information is received, go to step 10. If further information is not received within 30 days, go to step 9.	AST in TRS-SME
9	Send email to applicant informing that the file has been closed (template 5) and update SME database.	AST in TRS-SME
10	Create sign off sheet (template 1).	AST in TRS-SME
11	If submission is complete, go to step 12. If submission is not complete, go to step 5.	

Step	Action	Responsibility
12	Acknowledge receipt of response and update SME database.	AST in TRS-SME
13	Send email to HSer/AD to distribute submission for review.	AST in TRS-SME
High-level review of SME declaration and supporting documentation		
14	Check consistency of information in declaration form with supporting documentation (latest audited annual accounts/annual report(s) and upstream/downstream ownership), applicant's website (if applicable) and precedents/clarifications received on the SME definition (5.2.4 in DREAM). If a query arises relating to interpretation of EC definition of an SME, liaise as applicable with AD responsible within TRS-SME to send a request for clarification to AF-LD and/or designated contact point within the EC. Update SME database.	AST/AD in TRS-SME
15	If further information is required, go to step 16. If further information is not required, go to step 23.	AST/AD in TRS-SME
16	Request further information to be submitted within 30 days (template 3) and update SME database.	AST/AD in TRS-SME
17	If further information is received, go to step 21. If further information is not received within 15 days, go to step 18.	AST/AD in TRS-SME
18	Send reminder to reply to request for further information (template 4) to applicant.	AST in TRS-SME
19	If further information is received, go to step 21. If further information is not received within 30 days, go to step 20.	AST/AD in TRS-SME
20	Send email to applicant informing that the file has now been closed (template 5) and update SME database.	AST in TRS-SME
21	Check adequacy of responses and update SME database.	AST/AD in TRS-SME
22	If submission is complete, go to step 23. If submission is not complete, go to step 16.	AST/AD in TRS-SME
23	Finalise submission review (update database; sign-off sheet template 1) and inform AST as applicable.	AST/AD in TRS-SME
24	Send email for quality check of qualifications by HSer/AD/AST. For regulatory consultancy or companies annexed to a consultancy, attach SME qualification email (template 8).	AST in TRS-SME
Notification of SME status within 30 calendar days (excluding clarification phase between steps 5-11 and 15-20)		
25	Perform final quality check of qualification, update sign off for reviewed submissions only, and inform AST.	AST/AD/HSer in TRS-SME
26	Send qualification email from the database for EEA-based companies (template 9). For regulatory consultancy or companies annexed to a consultancy to the regulatory consultancy email SME qualification to the regulatory consultancy (template 8).	AST in TRS-SME
End of procedure		

10. Records

All documentation and correspondence is saved electronically in the appropriately labelled folder in DREAM.

Renewal qualifications generated by the database are saved in Outlook/All Public Folders/Chrono out/Chrono SME - Renewal qualification.

Renewal qualifications for regulatory consultancies and annexed companies are saved in DREAM in the regulatory consultancy folder and in Outlook/All Public Folders/Chrono out/Chrono SME - Renewal qualification.