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Annex 5 Draft Service Level Agreement

Procurement Procedure EMA/2012/13/ICT External Service Providers for
Software Applications: on-line analytical processing and reporting systems

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1. About this document

This document contains the draft service level agreements (SLA) for the service to be provided to the European Medicines Agency ("the Agency") under the framework contracts resulting from open invitation to tender no. EMA/2012/13/ICT for external service providers for software applications: on-line analytical processing and reporting systems.

The SLAs for both Lots 1 and 2 are included. The final agreed SLAs will form annexes to the framework contracts.

1.1. Glossary

Term	Description
Benchmark	In the context of this tender a benchmark is not a minimum requirement, rather it is a point of reference for a measurement.
CFT	Call for tender. In this document, used interchangeably with the term ITT
Charges	The amount payable covering all the services provided, exclusive of VAT
Contractor	A tenderer to which a framework contract has been awarded.
Evaluation Committee	A committee made up of staff from the European Medicines Agency ("the Agency") which is tasked with evaluating the tender responses. The committee may call upon technical experts for assistance; such experts may be non-Agency staff.
Fixed price orders	See Order types
FP	Fixed price
ITT	Invitation to tender. In this document, used interchangeably with the term CFT
Methodology	A collection of methods, practices, procedures and rules used by those who work in some field.
Online analytical processing and reporting systems	On-line analytical processing and reporting or data warehouse system is a database used for reporting and analysis. The data stored in this database is uploaded from the operational systems. The data may pass through an operational data store for additional operations before it is used in the DHW for reporting.
Order types	This ITT refers to three types of orders: Time and materials orders, which correspond to the order of a number of days for defined profiles Fixed-price orders, which correspond to an order for defined work Quoted time and materials, which correspond to the order of a number of days for defined

Term	Description
	subtasks
Quoted time and materials orders	See Order types
QTM	Quoted time and materials
Staff turnover	Turnover refers to the number of employees who have left the company within a given period of time – normally expressed as a percentage of the total staff employed and calculated annually
Standards	A rule or set of rules or requirements which are widely agreed upon and supported by an organisation regarded as authoritative.
Tenderer	An organisation or group of organisations which is submitting a response to this invitation to tender.
Time and materials orders	See Order types
Time and means orders	See Time and materials orders
Tools	This term is used in this document to describe software that facilitates the accomplishment of a task via simple deployment and configuration.

2. Draft Service Level Agreement Common to Lots 1 and 2

2.1. Agency contact information

Telephone numbers for the ICT Project Office are as follows:

Sherryll Eady	+44 20 7418 8683
Anita Zambrini	+44 20 7523 7247

Email of the ICT Project Office is as follows:

c-projectoffice@ema.europa.eu

2.2. Working hours

In general, Contractor personnel providing services at the premises of the Agency shall, unless otherwise agreed in writing between the parties, provide such services for eight hours per day. Contractor personnel will be present at the premises of the Agency between 09:00 and 17:30, and may take a lunch break between the hours of 12:00 and 14:00.

2.3. Agency holidays

The Contractor shall normally not provide the service on Agency holidays. Agency holidays are aligned with European holidays rather than UK holidays. Details of holidays currently planned for the period from 2013 to 2015 are attached in Annex 1 to this document.

2.4. Suspension of service

The Contractor should provide to the Agency every six months a schedule of periods when services are planned to be suspended for reasons of annual leave over the next six months. Where suspension of

services is unexpected or unplanned, a minimum of ten working days' notice must be given of periods when services will be suspended. The gap in service provision must be agreed in writing by the Agency's ICT Project Office. Agreement to a suspension must be sought in writing by the Contractor a minimum of ten working days before the first day of planned absence.

2.5. Notification of illness

If a member of Contractor personnel designated by the Contractor to undertake the performance of services is taken ill and is unable to come to the office, the Contractor shall notify the ICT Project Office before 09.30 on the first day of suspension of the provision of services and shall indicate when services will resume. The member of Contractor personnel in question should also notify the ICT Project Office at the Agency directly as a courtesy.

On expiry of the period without resumption of the service, the Contractor should telephone the Project Office again to say when suspension will be lifted.

The ICT Project Office will inform the relevant Agency Programme/Project Manager. The Agency Programme/Project Manager will inform colleagues in the ICT Sectors as required.

2.6. Timely submission of requests for reimbursement of travel expenses

Contractor personnel are required to submit requests for reimbursement of travel expenses to the Contractor as soon as possible after the travel has taken place, in order that the Contractor can comply with the deadline for submission of invoices to the Agency within two months of the date when travel took place. Contractor personnel are required to submit the originals of travel tickets and hotel invoices with their request for reimbursement. If tickets are lost and the Contractor personnel paid personally for them, a receipt for payment or a copy of a credit card or bank statement showing the purchase may, exceptionally, be submitted in place of the ticket.

2.7. ICT Standards

All services delivered will comply with the Agency's ICT standards described below.

2.7.1. The Agency's Information and Communication Technology Standards

The Agency develops and implements information systems in accordance with a defined set of technology standards. These technology standards are collected together in a formal document which is updated regularly via the Agency's ICT Standards Committee. The current version of the document is in **EMA-2012-13-ICT Technical Specifications - Annex 6, EMA DV Standards**.

The Agency's ICT standards include RUP@EMA, the standard methodology used at the Agency for developing software.

2.7.2. Reference Data Model

The reference data model is designed to be used as a prescription for the definition of the concepts for modelling of data during the design of new or old systems and to generate required exchange standards between systems and institutions. It:

- Defines the concepts that underlie the meaning of
 - Individual data elements; and
 - Constructs built up through the structured linking of individual elements;

- Sets out the parameters that constrain the way in which each element is used;
- Describes the relationships between elements to form the required constructs; and thus
 - Provides pre-defined elements and constructs for systems within the European Medicines Regulatory Network;
 - In a manner that supports the information needs and processes of the business of regulation of medicinal products in the EEA.
- For EU Telematics, it is being established in the form of:
 - A conceptual data model that includes information elements used in relation to all aspects of regulatory activity throughout the lifecycle of a medicinal product;
 - A physical implementation of the conceptual data model that defines the individual information elements in sufficient detail to ensure that any information system built to deal with any aspect of regulatory activity at any stage of a medicinal product's lifecycle would be able to draw the definitions of the elements, and the relationships between them, from the reference data model;
 - A physical implementation of the conceptual data model that includes the controlled terms, appropriately used in each context;
 - A physical implementation of the conceptual data model that is compatible with international standards agreed for implementation in the European Medicines Regulatory Network and
 - Confirmation from all stakeholders that the reference data model is the reference point for systems and exchange standards used in the European Medicines Regulatory Network.

2.8. Confidentiality Undertakings

Prior to commencing work, each individual allocated by the Contractor to work on a project will be required to sign the confidentiality undertaking set out in **EMA-2012-13-ICT Technical Specifications - Annex 9: Confidentiality Statement**.

These forms must also be completed and signed by contractors on non-full-time assignments. Declaration of interests forms need to be filled in on an annual basis.

2.9. Compliance with the business continuity planning

All Contractor personnel based at the Agency must comply with the requirements of the Agency's Business Continuity planning. These requirements will be advised to them on arrival at the Agency.

2.10. Health and safety briefing

All Contractor personnel based at the Agency must attend an Agency Health and Safety briefing within two weeks of their arrival or at the first available opportunity if no such briefing is scheduled during the initial two-week period.

2.11. Variations to this SLA

Any variation to the general terms must be agreed in writing between the Contractor and the Agency's ICT Project Office.

3. Draft Service Level Agreement for Lot 1

3.1. Process for ordering services

The ordering process for time and materials orders is as follows:

1. A profile specification for each profile required will be drawn up by the Agency and the template is included in **EMA-2012-13-ICT Technical Specifications - Annex 10: Standard Profile Specification & Request Form**. Where the Agency does not provide a profile specification, the default specification for the relevant profile (See document **EMA-2012-13-ICT Technical Specifications: Section 4.2.3. Detailed specifications of the profiles required**) will be considered by the Contractor.
2. A request form is completed by the Agency, in which the request for services is summarised and timelines are given for responses from the Contractor. A template example is included in **EMA-2012-13-ICT Technical Specifications - Annex 10: Standard Profile Specification & Request Form**.
3. The request form, accompanied by the profile specifications and any other relevant documentation is sent by e-mail to the first priority Contractor in the cascade.
4. If the first priority Contractor has been given the opportunity to provide these services and has failed to comply with the relevant timelines (as defined in this section and section 3.8.) or is unable to provide the services or has provided services unacceptable to the Agency (as defined in this section and section 3.8.), the Agency may send the documents to the next Contractor in the cascade and the process will continue until the request is satisfactorily fulfilled.
5. The Contractor is required to acknowledge receipt of the Request Form and associated documents by e-mail to the Agency within two working days of the date on which the Request Form was sent out by the Agency.
6. The Contractor is then required to indicate willingness to make an offer or to decline to make an offer by the date specified in the Request Form, which will be a maximum of 3 working days from the date on which the Request Form was sent out by the Agency (**Benchmark 1**). If the Contractor declines to make an offer or fails to respond by the due date indicating its willingness to make an offer, the Agency will then forward the Request Form to the next Contractor in the cascade.
7. Having confirmed willingness to make an offer, the Contractor is required to propose to the Agency by e-mail the CVs of candidates matching the requirements given in the profile specification form(s) accompanying the Request Form. The response must be sent to the Agency by the final offer date specified in the Request Form (**Benchmark 2**) with a formal confirmation from the Contractor that the proposed service has been verified by the Contractor to match the requirements. The Europass CV template must be used as per the Agency's instructions as set out in the annexes to the draft Framework Contract.
8. The Agency will assess the CVs. If no candidates are acceptable for an interview: see step 12 below.
9. If one or more CVs are found to be acceptable: all candidates proposed must be available for interview at the Agency in the two weeks following the sending of the CVs.
10. If the Contractor does not comply with the timelines specified, the Contractor will be deemed to have not respected the requirements and the Agency may forward the Request Form and documents to the next Contractor in the cascade.

11. If the Agency accepts a candidate(s) as a result of interviews, the Agency will send an e-mail to the Contractor indicating that the candidate(s) has been accepted and will request a formal offer from the Contractor. Having conducted up to 3 interviews without identifying a suitable candidate the Agency reserves the right to go to the next contractor in the cascade.
12. If a candidate(s) is found to be unacceptable to the Agency, the Agency will advise the Contractor by e-mail and will give feedback, wherever possible, on the reasons why the candidate(s) has been rejected. If the final offer date in the Request Form has not yet been reached, the Agency may permit the Contractor to forward more CVs for consideration. If the final offer date has been reached, the Contractor will be deemed not to have fulfilled the requirements (**Benchmark 3**) and the Agency may forward the Request Form to the next Contractor in the cascade.
13. Once a candidate has been confirmed and a formal offer received from the Contractor, the Agency will draw up the Specific Contract which will include the details of the work to be carried out, the start date, the duration in man-days and any other relevant information. The Specific Contract will be signed in the relevant number of copies by the Agency's signatory and will then be forwarded to the Contractor for signature. The Specific Contract becomes effective from the date of the last signature.
14. The Contractor will return one copy of the signed contract to the Agency, retaining the other copies for its own files.
15. Where a Specific Contract is already in place prior to the dispatch of a request for services (e.g. where there is a replacement of the Contractor's personnel), steps 13-14 will not apply.
16. The Contractor's personnel will commence work on a mutually convenient date and time and at the location stipulated in the Request Form. For time and materials contracts, this will normally be at the Agency's premises in Canary Wharf, London, UK.

The Contractor will be expected to present proposals which meet the requirements specified in the Request Form and associated documents. Personnel proposed must match the requested profile description and persons whose CVs have been proposed in the tender should be available to work on the Specific Contracts concluded with the Agency. The Contractor must present to the Agency **at least two suitably qualified candidates** for each profile required and these persons must be available for interviews, which are attended at the cost of the Contractor. Persons proposed must be available at the start date as identified in the Request Form.

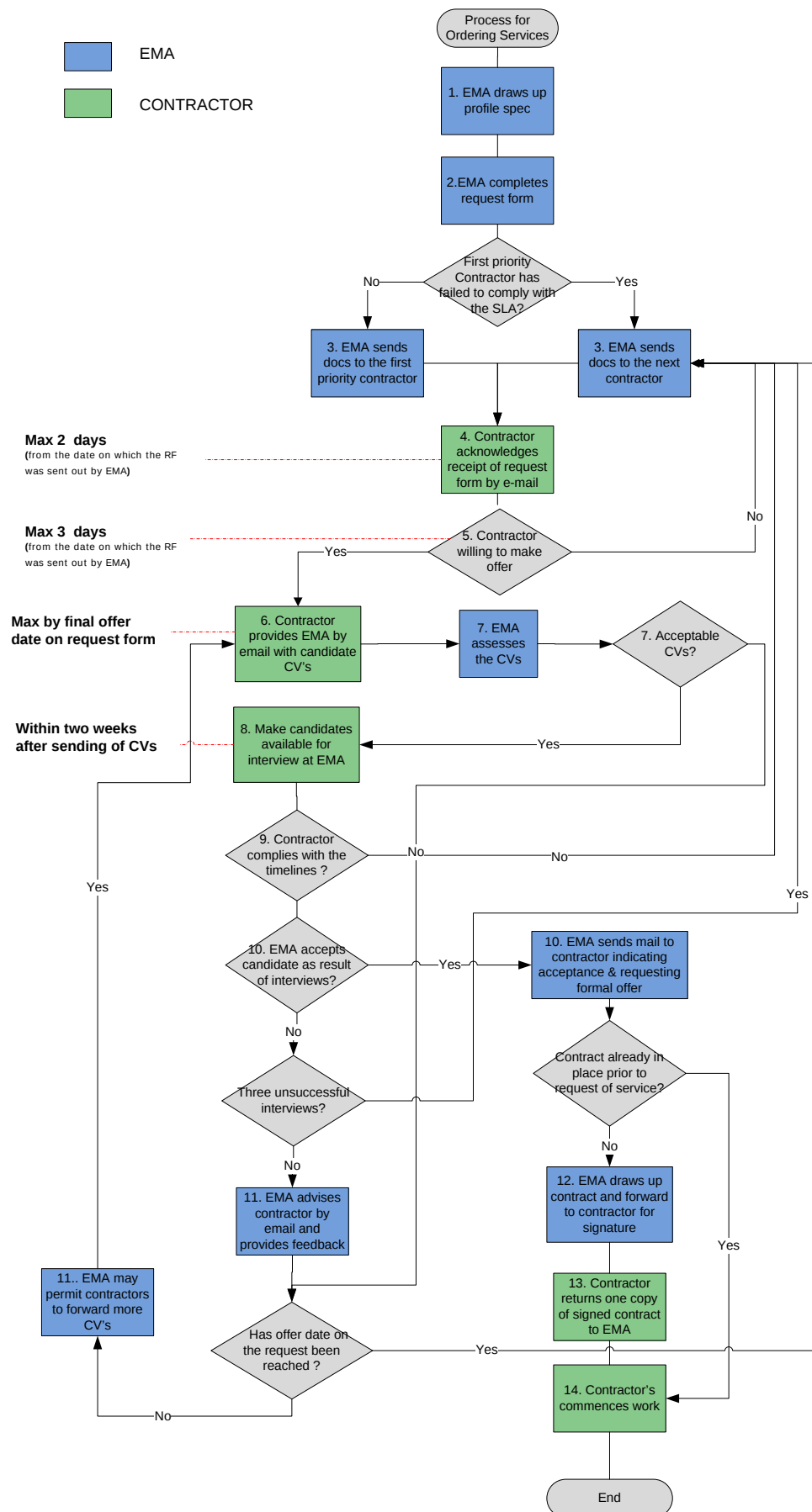


Figure 1: Diagrammatic presentation of the process for ordering services

Table 1. Benchmarks

Number	Purpose	Benchmark
Benchmark 1	For timely indication of willingness to make an offer or to decline	A maximum of 3 working days from the date on which the Request Form was sent out by the Agency
Benchmark 2	For timely provision of CVs	The response must be sent to the Agency by the final offer date specified in the Request Form
Benchmark 3	For success or failure to provide the requested service	If the final offer date has been reached without provision of acceptable Candidates, the Contractor will be deemed not to have fulfilled the requirements

3.2. Replacement of Contractor personnel not initiated by the Agency

Where there is a need to replace personnel and this is not initiated by the Agency, the following process shall be followed:

1. As soon as the Contractor learns that the original person will no longer be able to carry out the work, the Contractor is obliged to immediately inform the Agency. The Contractor shall give one month's notice (20 working days) to the Agency.
2. The process as described in section 3.1. Process for ordering services will be followed so that the replacement is present at Agency premises ten days before the end of the period of notice of the outgoing resource.
3. If the Contractor does not propose suitable replacement staff in due time, the Agency may:
 - 3.1. either immediately cancel the relevant profile from the SC, and invoke the cascade;
 - 3.2. or apply a penalty of 10 days free of charge.
4. The Contractor shall arrange sufficient training (during the handover period where possible) to guarantee continuity of the service provided to the Agency.
5. A handover of at least 10 working days, free of charge for the Agency, will take place.
6. If no handover is possible, at least 15 working days must be provided by the replacement person free of charge for the Agency. The days free of charge will be the first working days of the replacement person.
7. Any such replacement will be effected at no additional cost to the Agency.

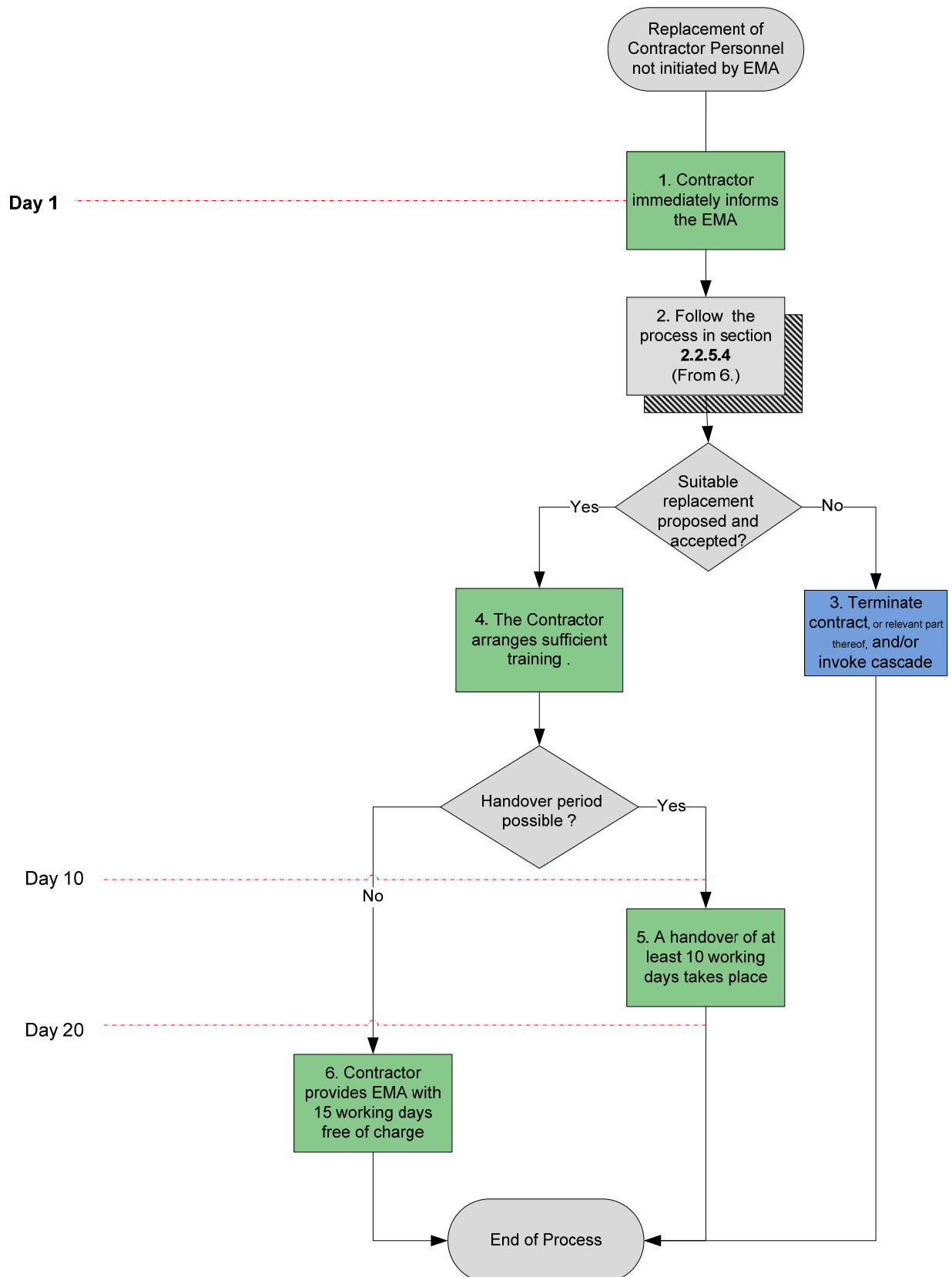


Figure 2: Diagrammatic presentation of the process for replacement

3.3. Languages

The required services must be provided in English.

3.4. Place of work

Work can be executed on an *intra muros* (see below) or *extra muros* basis (see below). There may be an occasional requirement for meetings outside the European Union (EU) and the European Economic Area (EEA) to be attended by Contractors' staff. The Agency will indicate on all Request Forms where the work has to be undertaken.

3.4.1. Intra muros

Intra muros work will be undertaken mainly at the Agency's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, UK. There may be a need for work to be carried out on the premises of the Member States Competent Authorities within the EU and the EEA, or at the premises of one or more of the Agency's industry partners. The infrastructure will be provided by the Agency.

Personnel providing the service will use only the standard software packages in use at the Agency, the named Member States Competent Authority in the EU or EEA or industry partner and no other software may be installed or used without the written authorisation of the Agency.

3.4.2. Extra muros

Extra muros work will be performed primarily at the Contractor's premises. Project meetings are typically held at the Agency's premises. Deliverables must be formally delivered at the Agency's premises.

The Contractor must provide all deliverables in the form and format specified in the order and shall guarantee their integration into the target informatics environment. In case of failure or difficulty to integrate the deliverables in the target informatics environment, the Agency may request the Contractor to provide the required corrective action at his own cost.

3.5. Time recording

Contractor personnel must record the hours worked in the Agency's time tracking system, EMA's implementation of Microsoft Project Server, Enterprise Edition in accordance with the instructions of the Programme / Project Manager responsible.

3.6. Maintenance of calendars

Contractor personnel are required to maintain the electronic calendar in Microsoft Exchange made available to them up to date. In particular, planned meetings and leave of absence should be introduced. Contractor personnel must give access to their electronic calendars to all EMA I-DV Sector staff.

3.7. Training of Contractor personnel

The Contractor will be required to ensure that the skills levels of personnel assigned to the Agency's projects are maintained throughout the period that they are working at the Agency. The Agency may require the Contractor to provide for the maintenance or enhancement of such skills levels for the individuals allocated to Agency activities through formal training at the cost of the Contractor. Such training is likely to require an average of 5 man-days per person per annum. The Contractor will be

expected to clear any proposed training with the Agency prior to commencement and to agree timings with the individual and with the individual's Programme/Project Manager before proceeding.

3.8. Quality monitoring

For the purposes of this section, a benchmark is a point of reference for the measurement of the performance of an activity against which the Contractor will be assessed.

The benchmarks defined below are used to measure the quality of the service delivery (See section 3.11. Service Quality Indicators and Service Quality Benchmarks)

Penalties may be imposed (See section 3.9.) where the Contractor either fails to meet quality expectations either by a substantial margin in a single instance or consistently over a period of time.

3.8.1. Quality of the service delivery

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations. CVs should meet the profile specifications in terms of the characteristics requested in the context of that which is described per profile in this invitation to tender and should be delivered in a timely manner. In addition, administrative activities in connection with setting up and maintaining the arrangements with individuals should be carried out in a timely and efficient manner. Finally, management of Contractor personnel should be pro-active and such that it contributes to efficient execution of projects and tasks.

The mechanism for monitoring will involve the periodic execution of the following:

- measurement of acceptability by means of invitations to an interview
- measurement of timely delivery of CVs
- measurement of the efficiency with which contractual arrangements are finalised with selected profiles in the context of known notice periods

Table 2. Benchmarks

Number	Purpose	Benchmark
Benchmark 4	For provision of qualitative CVs	An average of three acceptable (deemed compliant by the Agency with the profile description and/or invited for interview) CVs across all requests
Benchmark 5	For timely delivery (i.e. from step 6 - 13 above) of resources	An average of three weeks across all requests
Benchmark 6	For availability of resources	Availability of the resource, following the Agency's notification of intention to proceed, is no later than the known notice period, or two weeks where there is no notice period.
Benchmark 7	For compliance with notice period	Full compliance with the rule that requires the Contractor to provide the Agency with at least one month's notice (20 working days) when a resource discontinues his collaboration on an Agency project (e.g. because he has given the Contractor notice) where this is not desired by the Agency.
Benchmark 8	For audit success	The Contractor is expected to pass all audits by the Agency as per section 4.5.2. <i>Quality audits</i>

3.8.2. Quality of the work delivered by time and materials resources

Monitoring of the quality of work delivered by resources will measure the delivery of the services required in respect of their timeliness and the extent to which they meet the qualitative expectations of the Agency.

Monitoring will be carried out in the following manner:

Quality of the work of a resource

- Before commencing a task, the Contractor's personnel will agree on the scope of the task, the technical approach and the workload estimate with Agency staff.
- Progress monitoring: all resources will report on a weekly basis via timesheets showing the number of hours spent per agreed task and progress on the task.
- Monitoring of deliverables: upon delivery of a deliverable, Agency staff will review the quality of what is delivered on the basis of its fitness for purpose.

Table 3. Benchmarks

Number	Purpose	Benchmark
Benchmark 9	For quality of resources	An average of 1% per annum of all personnel of the Contractor currently providing services for the Agency to not meet expectations (See Note 1 below).
Benchmark 10	For turnover of resources	An average of 4% per annum of all personnel of the Contractor currently providing services for the Agency to leave the Agency where this is not desired by the Agency

Note 1:

Whether expectations are met will be established by adherence to the profile description (See section 3.1. 1), the service level agreement and the quality of code (*inter alia* established via peer reviews).

Where the resource either fails to meet the benchmarks by a substantial margin in a single instance or consistently over a period of time, the Agency may terminate the collaboration with this resource immediately. The Contractor will be required to replace the affected resource immediately.

3.8.3. Quality audits

The Agency will audit the Contractor's processes related to the delivery of the service. Three types of audits are foreseen.

- Short-notice point audit:
 - Notice period: 24 hours
 - Content: Request to provide documented evidence that a specific step in the processes related to the delivery of the service has been provided
 - Maximum frequency: One per month
- Shallow system audit announced in advance:
 - Notice period: 5 working days
 - Content: On-site (Contractor's premises) audit of all auditable processes and systems (cf. Infra)
 - Maximum duration: 0.5 days

- Maximum frequency: One per quarter
- In-depth system audit announced well in advance:
 - Notice period: 10 working days
 - Content: On-site audit (Contractor's premises) of all auditable processes and systems (cf. Infra)
 - Maximum duration: 2 days
 - Maximum frequency: One per year

The auditable processes will be part of the SLA with a possibility of revision on conclusion of Specific Contracts. The set of auditable processes and systems will consist of at least:

- The processes and systems required in this ITT
 - E.g.: The process described in sections 3.1. Process for ordering services, 3.2. Replacement of Contractor personnel not initiated by the Agency, 3.10. Reporting requirements
- The processes the Contractor has referred to in his response to this ITT as far as relevant to the delivery of the service.

3.9. Measures in cases of underperformance

If the contractor fails to meet the above benchmarks in respect of one or more of the quality indicators for a period of 3 consecutive months from the start date of the contract or during the preceding 12 month period, the Agency may decide to bypass the contractor for a period and to address requests for services to the next contractor in the cascade.

All profiles provided by the next contractor in the cascade as a result of the above measures will continue to be resourced by that contractor.

These measures will be applicable for a minimum of the next three service requests (irrespective of the type of profile) following the 3 consecutive months of failure to meet the benchmarks or until such time as the contractor has demonstrated that it has taken all necessary measures to remedy and resolve this situation.

The measures above may be applied under the following conditions:

- The period of measurement is the last 12 months or, if the duration of the framework contract is less than twelve months, from the start of the framework contract.
- The minimum number of requests must be 10 during the period of measurement.

At the end of the application of these measures, a new period of measurement of the quality indicators will be initiated.

3.10. Reporting requirements

The Contractor must provide the following reports to the Agency in English:

- Timesheets signed by individual contractors:
 - Using the standard Agency tool
 - Monthly
- Report on consumption per resource:

- A monthly report to be provided to the Agency's ICT Project Office detailing the number of man-days worked by each individual contractor working on time and materials contracts in the preceding month, including cumulative totals from preceding months and the number of man-days remaining on the individual's current assignment. This report must be provided by the end of the second calendar week of the month following the month to which the report refers.
- Report on quality of service delivery:
 - A quarterly report to be provided, by the end of the second calendar week of the month following the end of the quarter, to the Agency's ICT Project Office, detailing:

The number of requests received from the Agency

The number of requests fulfilled

Those outstanding at the end of the quarter

The number of candidates proposed for time and materials orders

The values of the benchmarks (see sections 3.1. Process for ordering services and 3.8. Quality monitoring)

The risks identified and the problems encountered (with the measures taken for the mitigation of risks and for correction of problems, and a follow-up of previous measures)

The exact content and layout of the respective reports shall be agreed between the Agency and the Contractor following signature of the Framework Contract.

Upon request of the Agency, Contractors will be required to attend a quarterly meeting at the Agency's premises in London to review performance, the status of the contract and the planning for the next period.

3.11. Service Quality Indicators and Service Quality Benchmarks

The quality indicators are defined in the table below:

Table 4. Quality indicators

Category	Service Quality Indicators		Reference to usage/point of measurement	Value	Service Quality Benchmarks
Process for ordering services	1	Compliance with timeline to indicate willingness to make an offer or decline	For every service request: Section 3.1. Process for ordering services: Step 6	Time [working days]	See Benchmark 1 in section 3.1. Process for ordering services: Step 6
	2	Compliance with timeline for sending the response	For every service request: Section 3.1. Process for ordering services: Step 7	Time [working days]	See benchmark 2 in section 3.1. Process for ordering services: Step 7
	3	Success or failure to provide the requested service	For every service request: Section 3.1. Process for ordering services: Step 12	Y/N	See benchmark 3 in section 3.1. Process for ordering services: Step 12

Category	Service Quality Indicators		Reference to usage/point of measurement	Value	Service Quality Benchmarks
Quality of the service delivery	4	Acceptability of the provided CVs	Every quarter across all service requests with a confirmed willingness to offer	Number	See benchmark 4 in section 3.8.1. <i>Quality of the service delivery</i>
	5	Timely delivery of resources	Quarterly average across all service requests with a confirmed willingness to offer	Time [working days]	See benchmark 5 in section 3.8.1. <i>Quality of the service delivery</i>
	6	Efficiency of finalisation of contractual arrangements	Quarterly average across all service requests with a confirmed willingness to offer	Time [working days]	See benchmark 6 in section 3.8.1. <i>Quality of the service delivery</i>
	7	Compliance with notice period	Quarterly average across all resources	Y/N	See benchmark 7 in section 3.8.1. <i>Quality of the service delivery</i>
	8	Audit success	Every quarter across all audit requests	Y/N	See benchmark 8 in section 3.8.1. <i>Quality of the service delivery</i>
Quality of the work delivered by time and materials resources	9	Quality of the provided resources	Quarterly average across all resources	Number	See benchmark 9 in section 3.8.2. <i>Quality of the work delivered by time and materials resources</i>
	10	Turnover	Quarterly average across all resources	Quarterly average across all resources	See benchmark 10 in section 3.8.2. <i>Quality of the work delivered by time and materials resources</i>

3.12. Use of the cascade

For ease of reference, this section repeats the cases in which and the mechanisms by which the cascade will be invoked and the duration or number of requests.

The Agency may decide to invoke the cascade:

- When the criteria for quality or timeliness as described in section 3.1. Process for ordering services, are not met for a particular request for services
- When the benchmarks as described in section 3.8. Quality monitoring, are not met for the duration or number of requests as specified in section 3.9. Measures in cases of underperformance.

4. Draft Service Level Agreement for Lot 2

4.1. Process for ordering services

The ordering process for fixed price or quoted time and materials orders is as follows:

1. The Agency draws up a specification of the services required and decides on the timelines for the responses from the Contractors.
2. The Agency sends a mini-call for tender to all Contractors in the pool.
3. The Contractor is required to reply with a tender in response to the mini-call for tender by the deadline indicated in the documentation.

3.1. For fixed-price orders¹:

- i. The Contractor must present proposals meeting the requirements as specified by the Agency in the Request Forms and associated documents (e.g. specifications, work packages, deliverables, activities, deadlines etc.).
- ii. The offer must include a technical analysis based on the requirements.
- iii. The offer must include a project plan. It has to indicate the proposed activities, the team structure, profiles, roles, responsibilities and workloads.
- iv. A methodology agreed by the Agency has to be used for the calculation of the workload of the different tasks. Based on this, the financial offer must be based on the estimation of the number of days for each activity.
- v. The deliverables must be on time, and conform to the specifications as described in the Specific Contract.
- vi. The invoicing is based on the acceptance of the deliverables by the Agency (and not on the effective workload).
- vii. Technical interventions can be foreseen on the Agency's premises for specific tasks like installations, configurations, acceptance tests, technical analysis or maintenance tasks.
- viii. Meetings at the location of delivery with members of the team can be required without any additional cost by the Agency.
- ix. A warranty applies to the deliverables accepted by the Agency.

3.2. For quoted time and materials orders¹:

- i. The Agency specifies the different tasks and sub-tasks to be executed and a total number of days for activities or profiles. When the request corresponds to activities, the Agency indicates the required activities with (or without) individual numbers of days. When the request corresponds to profiles, the Agency may specify (or not) the required profiles and their workload.
- ii. The Contractor must present proposals meeting the requirements as specified by the Agency in the Request Forms and associated documents (e.g. technical EMA-2012-13-ICT Technical Specifications: Annex with description of tasks, sub-tasks etc.).
- iii. The offer must include a technical proposal based on the requirements

¹ See glossary

- iv. The offer should detail the profiles, roles, activities, responsibilities and workload (activity-days or person-days).
 - v. The financial proposal has to be based on activities or profiles and their total workload.
 - vi. Contractor's staff must match the requested profile description.
 - vii. The work is divided into various sub-tasks performed during the execution of the specific contract. The Agency will provide the Contractor with a detailed description of each sub-task. The contractor will send the Agency a proposal for the execution of each sub-task (including the workload and time schedule) on the basis of a number of activity-days or person-days for the corresponding activities or profiles. The workload must be based on a methodology agreed by the Agency. When agreement with the Agency has been reached, a form is signed by both parties. Only agreed costs for the specified sub-tasks are chargeable, after acceptance by the Agency.
 - viii. Technical interventions can be foreseen on the Agency's premises for specific tasks like installations, configurations, acceptance tests, technical analysis or maintenance tasks.
 - ix. Meetings at the location of delivery with members of the team can be required without any additional cost by the Agency.
 - x. A warranty applies to the sub-tasks accepted by the Agency.
- 4. The submitted responses are opened and evaluated by an Evaluation Committee according to the award criteria stipulated in the documentation.
 - 5. The Agency confirms to the successful Contractor by email and letter that the offer is accepted and will form the basis of a Specific Contract.
 - 6. The Agency will advise the unsuccessful Contractors by e-mail and letter. Successful and unsuccessful Contractors will be advised at the same time.
 - 7. The Agency will draw up the Specific Contract which will include the details of the services to be provided, the start date, the duration, deliverables, price and any other relevant information. The Specific Contract will be signed in the relevant number of copies by the Agency signatory and then forwarded to the Contractor for signature. The Specific Contract becomes effective from the date of the last signature. The Contractor will retain the relevant number of copies for their files and return one copy to the Agency.
 - 8. The Contractor's personnel will commence work on a mutually convenient date and at the location stipulated in the Request Form. For Fixed Price contracts, this would normally be at the Contractor's own premises.

The Contractor must prepare proposals meeting the requirements as specified in the invitation to tender and associated documents. Deliverables must be on time and conform to the specifications as described in the Specific Contract.

4.2. Change management

Changes to the scope will be reflected in amended requirements (e.g. use cases) supplied by the Agency which will result in agreed amendments to the relevant Specific Contract.

4.3. Languages

The required services must be provided in English.

4.4. Place of work

For fixed price or quoted time and materials orders, the Contractor shall provide all the necessary infrastructure on the Contractor's premises for the successful execution of the work (except for material, licences or products not available on the market, but that can be provided by the Agency during the period of execution). Official acceptance of the work carried out will take place at milestones during and at the end of each order execution, using a procedure agreed to at the beginning of the order. Invoices may be issued only for executed orders and tasks that have been completed and duly accepted.

The Contractor must provide all deliverables in the form and format specified in the order and shall guarantee their integration into the target informatics environment. In case of failure or difficulty to integrate the deliverables in the target informatics environment, the Agency may request the Contractor to provide the required corrective action at its own cost.

4.5. Quality monitoring

4.5.1. Quality of the service delivery

4.5.1.1. Quality of the service delivery for fixed price contracts

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations.

Where the deliverable from the fixed price specific contract is to be a system or part thereof, the specifications in the specific contract will include at least the vision and system use cases prepared in accordance with the principles of RUP@EMA, as well as the requirements for documentation to be delivered with the system.

The monitoring of the quality of such fixed-price projects for software development will be carried out as follows:

1. At the outset of the project, a detailed software development plan will be drawn up by the Contractor following the principles of the Agency's RUP@EMA software development methodology. The deliverables of each iteration will be agreed between the Contractor and the Agency in the software development plan. This plan will be used by the Agency to measure the progress and quality of the project.
2. At the end of each iteration specified in the software development plan the Agency will test and approve the deliverables.
3. During the project, the Contractor will be required to provide regular progress reports containing:
 - An executive summary of the status of the project
 - The status of all the milestones.

Where there are delays, the reason(s) for the delay

Where there are delays, a revised end date

- The risk list, including:

A description of the risk

The probability, severity and consequence of the risk occurring

The mitigation plan for the risk

The current probability, severity and consequence of the risk occurring

- The list of issues
4. During the project, the system analysis and design documentation using UML must be reviewed and approved by the Agency's Software Architects. No deliverable will be accepted by the Agency without prior approval of the analysis and design documentation. The exact format of this documentation will be agreed in EMA-2012-13-ICT Technical Specifications: Annex to the relevant Specific Contract. An example of the type of documentation required is given below:
 - System use cases (where not provided by the Agency as part of the initial specifications)
 - Sequence diagrams for every use case and showing the interaction of all classes towards the realisation of that use case
 - Class diagram
 - Data model
 - Activity diagrams to illustrate the functioning of the important functionality of individual classes or of the system
 - Architectural diagrams
 5. During the project, the Contractor will be required to provide a test plan, test scripts, the results of the execution of the test scripts and a summary of the defects raised, offering the Agency sufficient assurance that the deliverables have been appropriately tested.
 6. After delivery and acceptance of the system, the Contractor will be required to finalise all the documentation to the Agency's satisfaction.
 7. On completion of the project, the measure of quality will be the number of defects in the deliverable against the relevant use cases for the system, taking into account the relative size and complexity of each use case.

Monitoring of the quality of fixed-price projects that are not software development projects will be undertaken using a combination of the above methodologies as applicable and as agreed in the relevant Specific Contract.

4.5.1.2. Quality of the service delivery for quoted time and materials contracts

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations. Measurement will be based on the quality indicators below.

Service Quality Indicator	
1	Respect of delivery dates
2	Conformance of sub-tasks delivered

4.5.2. Quality audits

The Agency will audit the Contractor's processes related to the delivery of the service. Three types of audits are foreseen.

- Announced shallow system audit:
 - Notice period: 5 working days
 - Content: On-site audit (Contractor's premises) of all auditable processes and systems (cf. Infra)
 - Maximum duration: 0.5 days
 - Maximum frequency: One per quarter or iteration
- Well-announced in-depth system audit:
 - Notice period: 10 working days
 - Content: On-site audit (Contractor's premises) of all auditable processes and systems (cf. Infra)
 - Maximum duration: 2 days
 - Maximum frequency: Two per specific contract. If there are amendments to the specific contract, one additional audit of this type can be executed per amendment

The auditable processes and systems will part of the SLA with a possibility of revision on conclusion of Specific Contracts. The set of auditable processes and systems will consist of at least:

- The application in practice of the software development process at the Contractor's premises where the subject of the contract is being developed.
- The systems used for:
 - Source code control, including version control
 - Defect management
 - Tracking from requirements to source code to testing artefacts
- The processes and systems the Contractor has referred to in his response to this ITT as far as relevant to the delivery of the service.

4.6. Measures in case of underperformance

The measures in case of underperformance will be specified in the specific contracts.

4.7. Reporting requirements

Please refer to section 4.5.1. *Quality of the service delivery*: Point 3 Reporting.

Annex 1 EMA holidays	2013	2014	2015
New Year's Day	01 January 2013	01 January 2014	01 January 2015
Day following New Year's Day	02 January 2013	02 January 2014	02 January 2015
Maundy Thursday	28 March 2013	17 April 2014	02 April 2015
Good Friday	29 March 2013	18 April 2014	03 April 2015
Easter Monday	01 April 2013	21 April 2014	06 April 2015
Labour Day	01 May 2013	01 May 2014	01 May 2015
Anniversary of Schuman Declaration	09 May 2013	09 May 2014	n/a
Ascension Day	09 May 2013	29 May 2014	14 May 2015
Day following Ascension Day	10 May 2013	30 May 2014	15 May 2015
Whit Monday	20 May 2013	09 June 2014	25 May 2015
Summer Bank Holiday	26 August 2013	25 August 2014	31 August 2015
All Saints' Day	01 November 2013	n/a	n/a
All Souls' Day	n/a	n/a	02 November 2012
Christmas	24 December 2013	24 December 2014	24 December 2015
	to	to	to
	31 December 2013	31 December 2014	31 December 2015
Notes:			
	1) Where n/a appears, this holiday falls on a Saturday or Sunday. These holidays are not replaced by another day when they fall on a weekend.		
	2) Holidays for 2014 and 2015 are currently draft and may be subject to minor amendments.		
	3) Holidays for 2016 and 2017 have not yet been published.		