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**EUROPEAN REVIEW SYSTEM
(EURS)**

**OPEN INVITATION TO TENDER
No. EMEA/2006/34/PM**

AND

SPECIFICATIONS

Version 1.0

No. EMEA/2006/34/PM	5
Title of the Invitation to tender	5
Objectives and Context of the Invitation to Tender	5
Subject of the Tender	6
Timelines	7
Location	7
Conditions of Delivery	8
Participation in the tender	8
Deliverables	8
Additional documentation available to tenderers	8
Variants	8
Price	9
Estimated contract volume	9
Currency of Tender	9
All-inclusive prices	9
Price Revision	9
Costs involved in preparing and submitting a tender	10
Period of Validity of the Tender	10
Protocol on the Privileges and Immunities of the European Communities	10
Payment Arrangements	10
Contractual Details	11
Procedure for Award of Contracts	11
Exclusion Criteria	11
Selection Criteria	12
Award Criteria	13
Presentation to the Evaluation Committee	14
Tender to be Submitted	14

Reply Address	16
Reply Procedure.....	16
Notes on the Format and Contents of the Technical Proposal	18
Technical Specifications (Requirements EURS v2.0)	19
Introduction.....	19
Purpose and Objectives	19
References	19
Definitions.....	20
Overview of the EURS	22
eCTD and EU Module 1	22
Scope of the EURS	23
EURS Requirements	24
Compliance with Standards	24
Functional Requirements	25
General Functional Requirements	27
Repository Requirements.....	28
Repository Download and Offline Features	30
Repository Extraction for Reporting	31
Administration Requirements	31
Validation of eCTD Submissions.....	31
View and LCM Requirements	35
View Requirements	36
LCM Requirements	40
Application Level	40
Submission Level	40
Search and Filter Requirements	42
Print Requirements.....	44
Review Requirements	46
Non-Functional Requirements	50
Technical Architecture	51
General Infrastructure Requirements.....	51

Infrastructure Requirements for the Central Repository	51
Infrastructure Requirements for the Administration and Review Tools.....	52
Software Product	52
Standard Product-related Services.....	54
Operations and Support Services	54
Software Maintenance Services.....	56
Additional Services (Training)	58
Annexes	59
ANNEX I – COSTING SHEET	60
ANNEX II - EXCLUSION CRITERIA STATEMENT AND DETAIL OF SUPPORTING DOCUMENTATION REQUIRED	61
ANNEX III – SUMMARY CHECKLIST OF DOCUMENTS WHICH TENDERERS MUST SUBMIT	63
ANNEX IV - DRAFT FRAMEWORK CONTRACT: SUPPLY AND SERVICE	64

Technical Specifications For Open Invitation to Tender
No. EMEA/2006/34/PM

Title of the Invitation to tender

This document contains the Open Invitation to Tender no. EMEA/2006/34/PM, European Review System (EURS).

Objectives and Context of the Invitation to Tender

This Invitation to Tender is for the provision of a supported eCTD validation and review tool for the EMEA¹ and National Competent Authorities² of the European Union that choose to implement it. The purpose of this open Invitation to Tender is to obtain sufficient information from potential suppliers to enable the EMEA to select an appropriate provider.

In the context of the International Conference on Harmonisation (“ICH”)³, an electronic exchange standard for the submission of regulatory information by applicants for marketing authorisations for medicinal products to the relevant competent authorities has been developed.

Based on the ICH Common Technical Document (CTD), the ICH M2 Expert Working Group has developed the electronic CTD (eCTD) Specification and released version 3.2 in February 2004. The eCTD release includes the Specification document as well as the relevant XML Document Type Definition (DTD) and can be found on the ICH web site (<http://www.ich.org> or <http://estri.ich.org/ectd/>).

The European Union applies the eCTD Specification in the European region and completes it with the European Module 1. The version 1.2.1 of the EU Module 1 Specification is expected to be released in August 2006 by the Telematics Implementation Group on electronic submissions (TIGes) and will be published on the TIGes working page. Tenderers should use this version of the EU Module 1 as primary reference as soon as the Specifications 1.2.1 have been published. Before such publication, version 1.1 remains applicable.

In order properly to implement the eCTD from the perspective of the EMEA and National CAs, a tool is required that will enable Competent Authorities that choose to implement it to receive, validate, store and make available for review marketing authorisation applications and supporting documents submitted electronically by applicants using the eCTD.

The EMEA has adopted a three-phase approach to the implementation of a European Review tool for eCTDs, comprising:

Phase I	July 2003 – December 2003	Basic system in place based on file server and a commercially available eCTD viewing solution. Limited implementation.
Phase II	December 2003 – November 2006	EURS v1.0, with a functionality as set out in the Requirements Document for EURS 1.0 (Final) published by the

¹ EMEA is the European Medicines Agency (“the Agency”), an agency of the European Union established under Council Regulation 726/2004. For further information, please consult the Agency’s website at www.emea.eu.int.

² The national bodies that administer the full spectrum of drug regulatory activities for countries of the European Union.

³ For further information on ICH, see www.ich.org

Telematics Implementation Group on Electronic Submissions (TIGes) in December 2002, in production for evaluation. Gathering of further requirements and subsequent implementation of EURS v1.1 via multiple tools, with more comprehensive functionality, as set out in specifications EMEA/2004/37/PM (October 2004). Implementation as wide as possible throughout the National Agencies of the EU.

Phase III After November 2006

EURS v2.0: Fully featured single-tool EURS in production. Based on full specifications completed as contained here following experience with the EURS v1.0/v1.1. Implementation as wide as possible throughout the National Agencies of the EU.

As part of this phased approach to eCTD implementation, the EMEA is issuing this Invitation to Tender to put in place the necessary software and services to enable the third phase of the implementation to continue after November 2006 with implementation of EURS v2.0.

The EMEA plans to commission the work as soon as is practicable following the tender closing date. The tender timetable is as follows:

- | | |
|-------------------------|---|
| ➤ 17 August 2006 | Notice dispatched to Office of Publications |
| ➤ 03 October 2006 | Closing date for receipt of tenders |
| ➤ 05 October 2006 | Meeting of the Opening Committee |
| ➤ 13 – 17 November 2006 | Dates between which short listed tenderers will be requested to attend at the premises of EMEA to demonstrate the software and answer any questions posed orally by the Evaluation Committee. |

Tenderers will be informed whether or not their tender has been accepted.

The EMEA anticipates that the assessment work will be complete, and the software commissioned by the conclusion of the contract at the end of December 2006

Subject of the Tender

The EURS software should enable European Union regulators to receive, validate, process review and manage the lifecycle of information in support of marketing authorisation applications submitted in eCTD format.

The Phase III implementation is designed to provide an advanced, intuitive and flexible level of functionality to as wide a selection of users in the community for the regulation of medicinal products in Europe as possible. To this end, the core requirements fall within the following areas:

- Compliance with standards
 - Worldwide standards e.g. eCTD
 - Regional standards e.g. EU Module 1
- General functional requirements

- This covers the organisation of the information, the multilingual support, the configurability, the multi-user approach, the logging capabilities
- Repository requirements
 - Use of a central repository (centralised architecture)
 - Possible evolution to a hybrid architecture
 - Offline capabilities, i.e. the partial copy of a submission to an offline computer, whilst retaining, in the copied part, the navigational possibilities for the full submission
 - Reporting capabilities
- Administration requirements
 - Initial processing, validation and loading of eCTD submissions
 - The management of a number of products
- View and Life Cycle Management requirements
 - Viewing capabilities, including navigation and localisation of the submission under review within the overall submission
 - Life Cycle Management support, i.e. The management of information relating to a number of regulatory activities intended to authorise and maintain changes to information (e.g. new application, supplements after questions, variations, etc.) pertaining to one product as one composite whole. Management of submission types throughout the life of the product
 - Search and filter capabilities within a submission
 - Print capabilities of a submission
- Review requirements
 - Copy, paste and annotations
- Non-functional requirements
 - Infrastructure requirements (system, repository, administration, review tool)
 - Interface with external systems (database and document repositories, and workflows for the management of regulatory activity on a submission)
 - Interoperability with additional systems already in place or to be implemented for the processing of specific sections of eCTD defined with further granularity e.g. processing of Product Information XML files (see <http://pim.emea.eu.int>) or the electronic application form (see <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex>)
 - Providing access and links to regulatory output (assessment reports; lists of questions etc.) from the associated submission documents
 - Software packaging
 - Standard product-related services (operations, support, maintenance, training)

The detailed requirements are laid out in this document in the section entitled ‘Technical Specifications’.

In addition to the tool itself, it is envisaged that training, training material and support will be provided as necessary to all users under the contractual agreement that will result from this Invitation to Tender.

Timelines

The tool and support services are to be provided from December 2006 on a renewable basis (for support and maintenance).

The selected tool should be made available for use by the EMEA and Competent Authorities by the end of 2006. Contractual and operational aspects should be in place by this time.

Location

The software is to be installed or made available by the chosen contractor at the EMEA in London and in all European National Competent Authorities that choose to implement it (National Competent

Authorities of the 25 countries of the enlarged European Union, and the 3 countries that comprise the EEA). The potential number of sites extends to a total of approximately 34 National CAs throughout all countries of the EEA. Provision should also be made for those countries set to enter the European Union in 2007 or later i.e. Romania, Bulgaria, Turkey and Croatia.

Conditions of Delivery

It is imperative that each installation is executed by the contractor on-site (if the architecture of the selected solution necessitates this), or that all necessary software and support is supplied to the EMEA and National Competent Authorities so as to enable successful installation with minimal expertise required and without the presence of the contractor.

Any specific contract for supply of software will only be considered as fulfilled once the software is fully commissioned at the site in question i.e. installed, tested and functional.

Participation in the tender

Participation in this tendering procedure shall be open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the European Communities in the field of public procurement under the conditions laid down in that agreement.

Where the Plurilateral Agreement on Public Procurement concluded within the World Trade Organisation applies (http://www.wto.org/english/tratop_e/gproc_e/agrmnt_e.htm), the tendering procedure shall also be open to nationals of the countries that have ratified this agreement, under the conditions laid down in that Agreement. In that connection, it should be noted that the services under Annex II-B to Directive DIR/2004/18/EC and the R&D services listed in category 8 of Annex II-A to that Directive are not covered by the Agreement.

Deliverables

The software and services requested through this Invitation to Tender comprise:

- eCTD processing and review software tool providing the functionality as laid out in these specifications
- A specification of hardware and software environment requirements on which to install the tool
- Training and provision of training material for all users
- Support and maintenance of the software (technical and user support) for the duration of the contract.
- Licenses

Additional documentation available to tenderers

Further information on the work of the EMEA can be obtained on its website: <http://www.emea.eu.int>. Please note that the extension for EMEA's external website addresses will change on 4 September 2006 from .emea.eu.int to .europa.eu

Variants

Not applicable

Price

Estimated contract volume

The software is to be installed or made available by the chosen contractor at the EMEA in London and in all European National Competent Authorities that choose to implement it (National Competent Authorities of the 25 countries of the enlarged European Union, and the 3 countries that comprise the EEA). The potential number of sites extends to a total of approximately 34 National CAs throughout all countries of the EEA. Provision should also be made for those countries set to enter the European Union in 2007 or later i.e. Romania, Bulgaria, Turkey and Croatia.

The contract volume further includes one year of support and maintenance for each installation site payable by EMEA. Support after the first year shall be the financial responsibility of the organisation on whose premises the installation has taken place.

Currency of Tender

All prices should be quoted in € (Euro), exclusive of VAT.

The cost breakdown should as a minimum distinguish between:

- the cost per user license (if applicable);
- installation (if applicable) and training costs, inclusive of travel, accommodation and subsistence costs;
- support costs.

The submission of a tender in response to this invitation to tender automatically implies the tenderer's acceptance of the terms and conditions stipulated in the invitation to tender, the current technical specifications and annexes including the draft contract. It also implies that the tenderer renounces his own terms and conditions. This is binding on the tenderer to whom the contract is awarded for the duration of the contract.

All-inclusive prices

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include delivery, supply and installation, maintenance, travel, subsistence and any other related expenses).

Price Revision

The contract is subject to price revision after the first year.

The charges shall be fixed and not subject to revision for specific contracts concluded during the first year of performance of the contract.

From the beginning of the second year of performance of the contract, the charges may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the contract became effective in accordance with Article I.2.1 above. Specific contracts shall be concluded on the basis of the charges in force on the date on which they become effective. Such charges shall not be subject to revision.

A revision shall be determined by the trend in European Index of Consumer Prices (EICP) published by the Statistical Office of the European Communities in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (<http://europa.eu.int/comm/eurostat/>).

Accordingly a revision shall be calculated in accordance with the following formula:

$$Ar = Ao \frac{Ir}{Io}$$

where

Ar = revised total amount;
Ao = total amount in the original tender;
Io = index for the month in which the validity of the tender expires;
Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices.

Costs involved in preparing and submitting a tender

EMEA will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be borne by the tenderer.

Period of Validity of the Tender

Tenderers must enclose a confirmation that the prices given are valid for six months from the date of submission of the tender. The EMEA expects to have reached agreement with the service provider within a reasonable period of the completion of the evaluation.

Protocol on the Privileges and Immunities of the European Communities.

EMEA is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

Payment Arrangements

Payment by the EMEA is upon presentation of invoice following sign off of agreed deliverables in respect of which the invoice is raised, giving a breakdown of the services or products supplied, and verified by the EMEA.

Payments shall be made within forty-five days of receipt of the request for payment and shall be deemed to have been made on the date on which they are debited to the EMEA's account. The EMEA may, however, after giving notice to the Contractor, defer payment if the products or services covered by the request for payment are contested by the EMEA or if the vouchers in support of the request are incomplete. Where payment is so deferred, the EMEA shall not be liable to pay interest or indemnities of any kind. All requests for payment and any complaints shall be sent to the following address:

European Medicines Agency (EMA)
7 Westferry Circus
Canary Wharf
London E14 4HB

EMEA shall be bound to comply with payment periods only if requests for payment are properly presented at the above address.

The Contractor is required to give the following information on all invoices:

(a) The breakdown of fees or quantities of goods supplied and the contract price and the amount of VAT applied, if any, or, whenever appropriate, the mention that the services rendered under the contract are exempted from VAT in conformance with the national tax law by which the contractor is governed.

(b) A reference to the contract number as shown on the first page of the Invitation to Tender (EMEA/2006/34/PM).

Contractual Details

A draft contract is attached to these Technical Specifications as Annex IV.

EMEA wishes to conclude a framework contract to provide service pertaining to the installation of maintenance of an eCTD review tool in EMEA and Member State NCAs as appropriate, as and when required, for a period of four years. Renewals are possible after this period for support and maintenance only. A framework contract will establish the terms governing specific contracts (purchase orders) to be awarded during a given period, in particular with regard to price.

Signature of the framework contract imposes no obligation on EMEA to order services. Only the implementation of the framework contract through specific contracts (purchase orders) is binding for EMEA.

Each specific contract will contain details of deliverables and timelines for particular services to be provided.

Procedure for Award of Contracts

The procedure for the award of contracts consists of three successive operations:

- Ascertaining whether any tenderers should be excluded in accordance with the criteria below;
- Checking potential contractors' financial and economic standing and technical and professional competence on the basis of the selection criteria; and
- Comparing tenders on the basis of the award criteria.

Exclusion Criteria

Tenders shall be excluded from participation in this procurement procedure if:

- they are insolvent (or the subject of bankruptcy proceedings if an individual) or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- they have been convicted of an offence (if an individual) or judgment has been made against them concerning their professional conduct by a judgment which has the force of res judicata;
- they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;

- they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Community's financial interests;
- following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

- are subject to a conflict of interest;
- are guilty, either knowingly or negligently, of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information.

Tenderers must complete the declaration in Annex II in relation to Exclusion Criteria and provide all the supporting documentation indicated in this Annex.

Selection Criteria

Financial and Economic Capacity

Tenderers are requested to provide the following documentation to enable an assessment of their financial and economic capacity.

If the tenderer is a company and is otherwise required under the law of the State in which it is established to publish its accounts, the following information is requested:

1. A copy of the most recent audited accounts that cover the last three years of trading or for the period that is available if trading for less than three years.
2. A statement of the company's turnover, Profit & Loss and cash flow position for the most recent full year of trading (or part year if full year not applicable) and an end period balance sheet, where this information is not available in audited form at point 1 above.
3. Where documents mentioned under point 2 cannot be provided, please provide a statement of the company's cash flow forecast for the current year and a bank letter outlining the current cash and credit facility position.
4. If the organisation is a member of a group of companies, documents under points 1, 2 and 3 are required for both the tenderer and its ultimate holding company. Where a consortium or association is proposed, the information is requested for each member company.
5. Please enclose a separate statement of the tenderer's turnover that relates directly to the requirements EMEA for the past three years, or for the period the tenderer has been trading (if less than three years).
6. Evidence of professional risk indemnity insurance.

If the tenderer is not obliged to publish its Accounts under the law of the state in which it is established, please supply copies of such accounting information as the tenderer is willing to

provide relating to the last three financial years or any period since the end of the last financial year.

Technical and professional capacity

Tenderers are requested to provide the following documentation to enable an assessment of their technical and professional capacity:

- Proof of authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.
- Details of staff turnover during the last financial year: total staff turnover and percentage of staff that have worked within the relevant business area for over 3 years.
- Details of registration with professional or trade registers of the state in which the tenderer is based under conditions laid down by that state. If any evidence is attached, please indicate clearly to which question number they apply and state that it is provided below.
- A description on a separate sheet (maximum 400 words) of previous experience relevant to the requirements of EMEA.
- A statement of the tenderer's policy on the use of sub-contractors, and of the means of ensuring quality when sub-contractors are used. A confirmation whether or not sub-contractors will be used for this contract and if so the full name and address of the sub-contractor(s) and the intended percentage of the contract which would be sub-contracted.
- Details of any quality assurance accreditation that the tenderer holds. If no accreditation held, please provide an outline of any quality assurance policy.

Award Criteria

Responses to this invitation to tender will be evaluated using the following award criteria and weighting:

Criterion	Weighting
(a) Appropriateness of the proposed solution (including installation, training and maintenance) in consideration of the current situation vis à vis eCTD processing and review at the EMEA and in Member State National Competent Authorities;	20%
(b) Clarity of response to the Invitation to Tender and understanding of requirements of the Invitation to Tender;	15%

(c)	Extent to which the core technical requirements set out in this specification can be met;	15%
(d)	Quality and relevance of the proposed support;	15%
(e)	Completeness of compliance with the support requirements set out in this specification;	15%
(f)	Quality and relevance of the training model proposed	10%
(g)	Extent to which additional functionality is proposed	10%
(h)	Most economically advantageous tender with regard to the overall value for money.	The benefits to the EMEA for each tool will be established by calculating the average number of marks attained by a tool across all members of the evaluation committee across all weighted award criteria (a) – (g). The cost of installing and maintaining the tool at each installation site for one year will then be calculated, and from this a cost of the tool over a 5-year period will be extrapolated. The cost: benefit ratio per year can then be established.

Presentation to the Evaluation Committee

All short listed tenderers will be asked to attend a meeting at EMEA premises in the week of 13th November 2006. This presentation is mandatory and if any tenderer declines to give a presentation, it will be automatically eliminated from the procedure. Tenderers will be asked to present an overview of their proposal and to demonstrate the tool itself. Members of the evaluation committee should also be given the opportunity to gain practical experience with the tool at this meeting.

The presentation/demonstration will be used to review and finalise the marks corresponding to the award criteria above, which will have been provisionally awarded on the basis of prior evaluation of the written proposal.

Tender to be Submitted

In order to assess each tenderer according to the above-mentioned criteria, the following information must be submitted by the tenderer:

- A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
- An information sheet on the tenderer indicating:
 - the name and registered business address including telephone and fax numbers, e-mail address and website address;
 - any other different current or previous trading name;

- the name and contact details of the person whom may be contacted with any queries regarding this tender;
 - the legal status of the tenderer;
 - if the tenderer is a partnership the full details of the partners;
 - if the tenderer is a company the company registration number, VAT registration number and date of incorporation;
 - if the tenderer is a member of a group of companies and if so the relationship between the tenderer and the ultimate holding company, the name and address of the holding company and its registration number, whether the ultimate holding company would be prepared to guarantee the liabilities in connection with this contract;
 - details of organisational structure including organisation chart;
 - number and locations of premises;
 - number of employees;
 - name of the person authorised to sign contracts on behalf of the tenderer.
- Completed questionnaire in Annex II relating to Exclusion Criteria AND supporting documentation.
- Documentation requested to enable assessment of Selection Criteria.
- Documentation requested to enable assessment of Award Criteria including the Technical Proposal.
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with EMEA.
- An undertaking to inform EMEA promptly following any matter which would alter or add to any of the information given in response to this tender.
- Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex I, and exclusive of VAT, signed by an authorised representative of the tenderer.
- Tenderers are requested to make use of the checklist given in Annex III to ensure that no enclosure has been omitted in their tender.
- Tenders must be perfectly legible to avoid any doubt about terms and/or figures included.
- Tenderers must make use of the costing sheet enclosed in Annex I.
- Tenderers must note that this invitation to tender does not constitute any contractual obligation on the part of EMEA. Such obligation only commences upon signature of a contract with the successful tenderer.

EMEA may, until the contract is signed, withdraw from the contract or cancel the procurement procedure without any compensation to tenderers. In such a situation a decision to cancel would be notified to all tenderers.

Reply Address

Interested tenderers should submit a proposal by 03 October 2006 to the following address:

The European Medicines Agency
Att.Claire Edwards – Project Management
7 Westferry Circus
Canary Wharf
London E14 4HB
U.K.

Please note that in the case of delivery by hand or by courier service, the envelope should be addressed as set out in “Reply Procedure” below but delivery must be made to the following address:

EMEA
1-7 Westferry Loading Bay
Ontario Way
Canary Wharf
London E14 4HB
UK

Reply Procedure

Tenders must be:

- (i) On paper, in duplicate; and
- (ii) Supplied in electronic form, in duplicate, on CD. Please note that no tender may be submitted by electronic mail. Any tender received by electronic mail will be automatically eliminated from the procedure.

You may submit your tender:

- (a) either by registered mail or by courier service, posted not later than 03 October 2006 (the date of the postmark or the date of the deposit slip with the courier service serving as proof of posting date/time); or
- (b) by hand delivery (in person or by an authorised representative or private courier service) to the EMEA at the above address to arrive not later than 17:00 on 03 October 2006. In the case where deliveries are effected by hand, the deadline to be respected shall be the date and time of delivery and not the transmission/deposition by the tenderer to its representative. The said delivery must be effected against a dated and signed receipt given by a member of staff of EMEA.

Tenders must be submitted in two envelopes which are sealed. The sealed envelopes should be marked: **"Invitation to Tender no. EMEA/2006/34/PM, Attn. Project Management - Not to be opened by the internal mail department "**. These sealed envelopes should be addressed to the department indicated in the invitation to tender. If a self-adhesive envelope is used, it must be sealed with adhesive tape and the sender must sign across this tape.

Boxes may be used instead of envelopes if the size or weight of the tender so requires.

Any financial element (including costing sheet) must be submitted in separate binders or folders, which must be clearly labelled. Information relating to this element should be given nowhere else in the tender.

If an electronic copy of any elements has been requested, these should be provided on separate hard supports (e.g. diskette, CD-ROM).

Contacts between EMEA and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

Before the final date for submission of tender:

At the request of the tenderer, EMEA may provide additional information solely for the purpose of clarifying the nature of the contract. Should a tenderer have a question, this should be submitted in writing (by letter, fax or by e-mail) to:

Claire Edwards – Project Management
EMEA
7 Westferry Circus
Canary Wharf
London E14 4HB
Email: claire.edwards@emea.eu.int
Fax: +44 207 418 8670

Requests for additional information received less than five calendar days before the closing date for submission of tenders will not be processed for practical reasons.

EMEA may also, on its own initiative, inform tenderers of any error, inaccuracy, omission or other clerical error in the text of the contract notice, invitation to tender letter or technical specifications and their annexes.

Any additional information including that referred to above will be made available in an identical manner simultaneously to all tenderers.

After the opening of tenders

If clarification is required or if obvious clerical errors in the tender need to be corrected, EMEA may contact the tenderer provided the terms of the tender are not modified as a result.

Tenders will be opened at EMEA's premises on 5th October at 10am. One representative per tenderer is permitted to be present at the opening of the tenders. The name of any such representative is to be notified at least 24 hours in advance in writing to EMEA to Claire Edwards at the address given above.

All tenderers will be informed of the outcome of their tender.

EMEA has published a Guidebook for Tenderers which may be downloaded from its external website at <http://www.emea.eu.int/contracts.htm>.

Notes on the Format and Contents of the Technical Proposal

- a) **Project Approach:** The implementation strategy should be explained, together with the reasoning underlying its formulation.
- b) **Proposed Technical Solution:** In this section, tenderers are expected to demonstrate their understanding of the tender requirements, and to show how these requirements are met by the existing software. Each requirement should be addressed individually. Where the tenderer feels that the requirement is capable of being interpreted in more than one way, and no clarification has been sought or received from the EMEA, the tenderer should clearly state what is understood by the requirement for the purposes of his tender. The submission should describe the software architecture of the proposed solution. The tenderer should also indicate the extent to which the infrastructure requirements constrain the proposed solution, including in particular any relaxation that may be advantageous, and the reasons why. Tenderers should confirm that the proposed solution complies with the EMEA's Standard Methodology and Tools or detail any areas in which the proposed solution might not comply.
- c) **Support and maintenance:** The proposal should clearly demonstrate the human resources and infrastructure to be allocated to supporting the software in Europe for the duration of the contract.
- d) **Key Assumptions and Dependencies:** Any assumptions derived or made by the tenderer which underlie the proposal, which affect the basis of the proposal, and which have not been made explicit in these specifications should be clearly stated, together with an estimate of the impact on the proposal, should the assumption not hold.
- e) **Project Planning (Work Breakdown Structure, Project Gantt Chart and Milestones):** The proposed project planning should deal with both timing and resource allocation issues. In particular, input from EMEA personnel and Member State CAs should be identified and quantified, as should any user input. It should be noted that users will be both internal and external to the EMEA.
- f) **Project Management:** This section should provide a description of the project management methodology to be adopted in executing the proposed contract.
- g) **Project Team/Effort Estimates:** This section should be compiled in such a way that the consistency between the data in these sections and the high-level outline plans presented is immediately apparent to evaluators of the tender. The consistency between these sections and the costing proposals should also be immediately apparent.
- h) **Estimated EMEA and stakeholder effort:** Clear indications of the tenderer's assumptions relating to the extent to which stakeholders e.g. EMEA and other regulatory staff (Member State experts; contributors from the pharmaceutical industry) will be required to contribute to the project should be provided.
- i) **Quality Assurance Approach:** The tenderer should outline his quality plan, ensuring that each major item is addressed. The project quality plan should include a clear description of the quality assurance procedures that will be in place to ensure delivery of the project

Technical Specifications (Requirements EURS v2.0)

Introduction

Knowledge of both eCTD and EU Module 1 Specifications is necessary for an understanding of these requirements. Both specifications use XML technology and are considered exchange standards. In other words, each specification defines how regulatory information is passed from the pharmaceutical industry to the regulatory authorities, but it neither defines how the exchange standard is generated by the applicant, nor how it will be used and viewed by the authorities. The consequence of this approach is that in order to receive, validate and review eCTD-compliant applications, regulatory authorities need to have a system in place.

Purpose and Objectives

It is the intention of the EU to use an eCTD review system common to the EMEA and EU Member States, which is flexible enough to cope with the variety of ICT infrastructures and eCTD readiness within the different Member States. The EURS therefore should have the ability to be integrated in individual Member States information systems, from the very simple to the more sophisticated. The present document describes compliance with standards and specifications, as well as functional and non-functional requirements for the EURS system.

References

The EURS should be based on the following published standards:

- Electronic Common Technical Document Specification, version 3.2
Cf. the ICH web site at <http://estri.ich.org/ectd/>
- ICH List of Validation Criteria
Cf. Q&A Document at <http://estri.ich.org/ectd/>, with reference to Question 36 and the list of criteria as set in the worksheet "Q&A No. 36"
- EU Module 1 eCTD Specification, versions 1.1 and 1.2.1
Cf. the EudraLex web site, under the Notice to Applicants section, Volume 2B - eCTD at <http://europa.eu.int/comm/enterprise/pharmaceuticals/eudralex/homev2.htm>
- EMEA Standard Methodologies and Tools, version 9.0
Vendors should state whether or not their proposals comply with the EMEA Standard Methodologies and Tools, and if not fully, areas of non-compliance should be stated.

The EU Module 1 makes reference to:

- Electronic Application Form (eAF) for New Applications, version 2.0
Cf. the EudraLex web site, under the Notice to Applicants section, Volume 2B - eCTD at <http://europa.eu.int/comm/enterprise/pharmaceuticals/eudralex/homev2.htm>
- Electronic Application Form (eAF) for Variations, version 1.0
Cf. the EudraLex web site, under the Notice to Applicants section, Volume 2B - eCTD at <http://europa.eu.int/comm/enterprise/pharmaceuticals/eudralex/homev2.htm>
- Product Information Management (PIM), versions 2.0, 2.0.1, 2.1, 2.1.1 and 2.2
Cf. the PIM web site hosted at the EMEA at <http://pim.emea.eu.int/>

Definitions

This section provides the definition of the most important terms used in these technical specifications. Additional definitions may be found in the Specification documents referred into above.

Term	Definition
Application	Application for the approval of a new medicinal product, or changes to the approved information for that product. This may be a new variation, submission of a PSUR or a licence renewal An application may consist of several individual submissions or sequences
CTD	<i>Common Technical Document</i> Specification for applications for approval designed to be used across Europe, Japan and the U.S
DTD	<i>Document Type Definition</i> Description of XML documents, in terms of constraints on the structure of those documents
eAF	<i>Electronic Application Form</i> XML format for the submission of the application form in the EU, including new application, variations, renewals...
eCTD	<i>Electronic CTD</i> Data exchange standard for the electronic submission of CTD information
EU	<i>European Union</i>
EURS	<i>EU Review System</i> The proposed European review system for eCTD submissions
ICH	<i>The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</i> Organisation that brings together the regulatory authorities of Europe, Japan and the United States (and Canada as observers), and experts from the pharmaceutical industry in the three regions, to discuss scientific and technical aspects of product registration
Life Cycle Management	The management of all regulatory activities for a particular product, representing the approval of a marketing authorisation application and the subsequent changes to this approval over time.

Term	Definition
	As a term this excludes processes used by applicants to manage documents and information internally
PIM	<i>Product Information Management</i> XML format for the submission and exchange of product information (part of the overall marketing authorisation application) in the EU Centralised procedure
Product	Term used to reference the medicinal product for which the marketing authorisation application is being submitted to the agency
SPL	<i>Structured Product Labelling</i> An exchange format based upon the capabilities of the extensible markup language (XML) for the submission of the content of labelling (Package Insert or Professional labelling) in the US
STF	<i>Study Tagging File</i> XML format for the submission of study reports in the US within the eCTD
Submission	Specific set of information on a product (a specific set of formulations, strengths and presentations) that is transmitted to the Agency for review and approval. An Application follows a path of an initial submission followed by a cycle of reviews and responses until approval. Except for the first submission of a product, a submission is always based on a previous submission for the same product An eCTD submission equates to a sequence, as per the ICH specification Sequence/submission 0000 is the initial submission relating to the first application for a marketing authorisation using eCTD Following Sequences/submissions (0001, 0002... using a continuous increasing numbering) contain responses to questions from the regulator, a variation application or an activity for the approved product

Overview of the EURS

eCTD and EU Module 1

An eCTD submission consists of the following files:

- An XML file, the eCTD backbone, which currently provides a series of references to content files providing hierarchical organisation of these files as well as their life cycle management
- A hash file that contains the MD5 signature of the eCTD backbone
- PDF files that are part of the submission, with operation attributes (attributes of a leaf that are added by the applicant in order to show the relationship between leaf elements over the product lifecycle), according to the life cycle management rules
- Other files submitted as part of the Module 1 (see below)

The eCTD backbone is always organised in 5 modules. Modules 2-to-5 are defined at the ICH level (worldwide) while Module 1 is region-specific.

The common (worldwide) modules apply the same following principles:

- A Module provides a hierarchical organisation of files, which is defined in the eCTD DTD
- The hierarchical organisation terminates with leaf elements, which are used to refer to external files that belong to the submission. Those leaf elements also support the life cycle management features
- Files are submitted mainly in PDF format, but other file formats are accepted in line with the eCTD specifications
- A submission contains only information that has changed since the previous submission (concept of delta). Previous submissions are referenced through the operation attributes.

There is one Module 1 per region (at least for Europe, US and Japan). For Europe, the Module 1 contains 2 elements that may be submitted in XML instead of PDF or RTF:

- The Electronic Application Form (eAF)
- The Product Information (PIM)

Scope of the EURS

The scope of the EURS is to enable the European Regulators in validating, viewing and reviewing eCTD submissions taking advantage of all the features of eCTD. This includes:

- The eCTD itself, including
 - Support of the leaf elements and the life cycle management
 - Support of the node extensions
- The files referred from the eCTD backbone
- The EU Module 1 XML file, its content and the PDF files it refers to

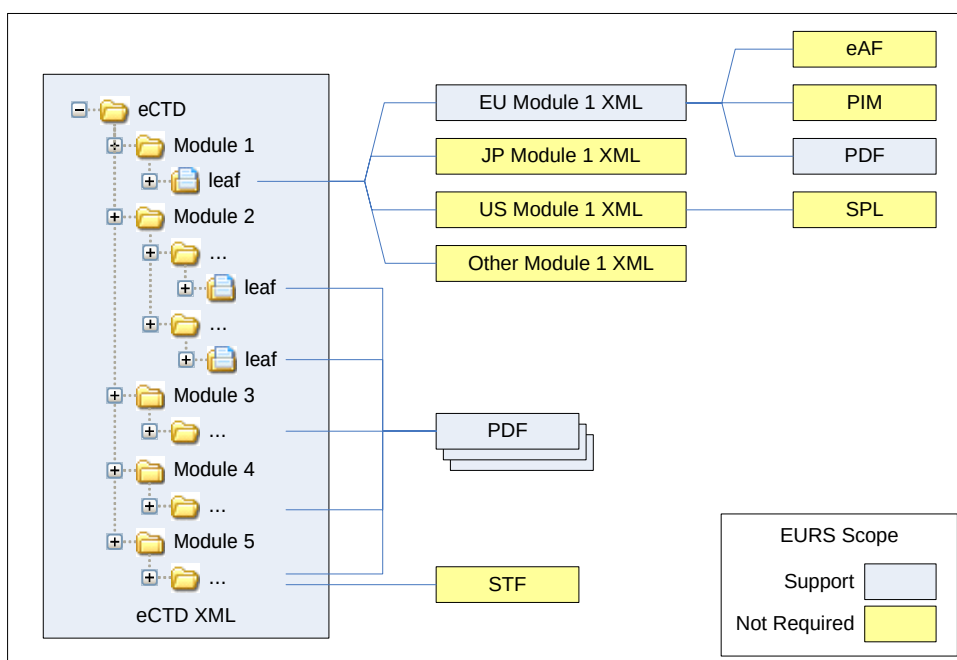
The EU Module 1 also may contain additional structured information (relying on XML) such as the application form (eAF) or PIM. There is no requirement for the EURS to support the review of this information except that the EURS should be flexible enough to

- provide a view the content of this information using the in-built display capabilities of the eAF and PIM standards (i.e. style-sheet)
- allow the application(s) dedicated to the review of the eAF / PIM information to be invoked, used, and closed again within the EURS itself

Other instances of the Module 1 (US, Japan...) should be ignored by the EURS but their presence should not block any functionality of the EURS and no message related to these Modules should be shown (e.g. validation error of the US Module 1).

The eCTD should also refer to Study Reports using the STF format. Such format is not used in the EU and therefore the EURS may ignore STF files but their presence should not block any functionality of the EURS and no message related to these files should be shown.

The scope of the EURS is summarised in the figure below.



EURS Requirements

Compliance with Standards

The EURS is intended to be a review system that supports relevant worldwide and regional standards as set out in their related specifications. Therefore, the compliance of EURS with these standards and specifications is a key requirement.

ID	Requirement
SPEC01	The EURS must comply with the international and regional standards (e.g. DTD) and specifications (e.g. folder structure, file naming convention...) that are relevant in the scope of the eCTD: – ICH eCTD version 3.2 – ICH List of Validation Criteria (Q&A 36) – EU Module 1 Specification versions 1.1 and 1.2.1 The EURS will validate the compliance to these standards and specifications via a validation module (see section Validation).
SPEC02	The EURS must utilise the life cycle information as defined in the eCTD and EU Module 1 specifications. The exploitation of the life cycle management is to be provided in the context of the different views provided in the review part of the EURS (see section "Review Requirements").
SPEC03	The EURS must support the following EU regional standards and specifications: – PIM DES specification from version 2.0 – Electronic Application Form (eAF) specification for new applications version 2.0 – Electronic Application Form (eAF) specification for variations version 1.0 – The EURS should be open to support additional EU regional standards in a similar way when integrated into the EU Module 1 The EURS should not provide specific review features for these standards but provide invocation and integral use of dedicated review tools (see section Overview of the EURS).
SPEC04	The EURS can, but need not necessarily, comply with specifications of other regions (Study Tagging File, Structured Product Labelling, Japanese standards...). This must not however impact a functionality related to an ICH or EU specification, e.g.: – The EURS shall never provide information on or block for non-compliance in respect of a specification not related to ICH or EU – The EURS shall not validate US Module 1 (no validation of us-regional.xml file) or the JP Module 1 (no validation of jp-regional.xml file). The tool should not report any information relating to any component of the eCTD not relevant to the EU.
SPEC05	The EURS must support all file formats defined as valid formats in the eCTD or EU Module 1 standards and specifications
SPEC06	The EURS must comply with the latest published version of the eCTD and EU Module 1 standards and specifications (see section 'References'). The same applies to the additional EU regional standards and specifications, if they are supported, referred in CS03.

ID	Requirement
SPEC07	The EURS should support submissions built using the current and all the previously published eCTD and Module 1 standards and specifications. The EURS should support any combination of applicable versions of the worldwide (e.g. eCTD) and regional (e.g. EU Module 1) standards.
SPEC08	When a new version of a standard is published, updated EURS versions must not endanger the treatment of eCTD submissions that have been received using one of the previous versions of the standard(s). The EURS shall be backwards compatible and be able to support historical data as such. The EURS should support any combination of applicable versions of the worldwide (e.g. eCTD) and regional (e.g. EU Module 1) standards. The EURS should not rely on an automatic or immediate update of applicant systems when a new version of a standard is released. The support of new versions applies to all standards under the eCTD umbrella, and cover among others the electronic application form (eAF), the product information management (PIM)...
SPEC09	The EURS must support the verification of the version of standard being used in an eCTD submission.

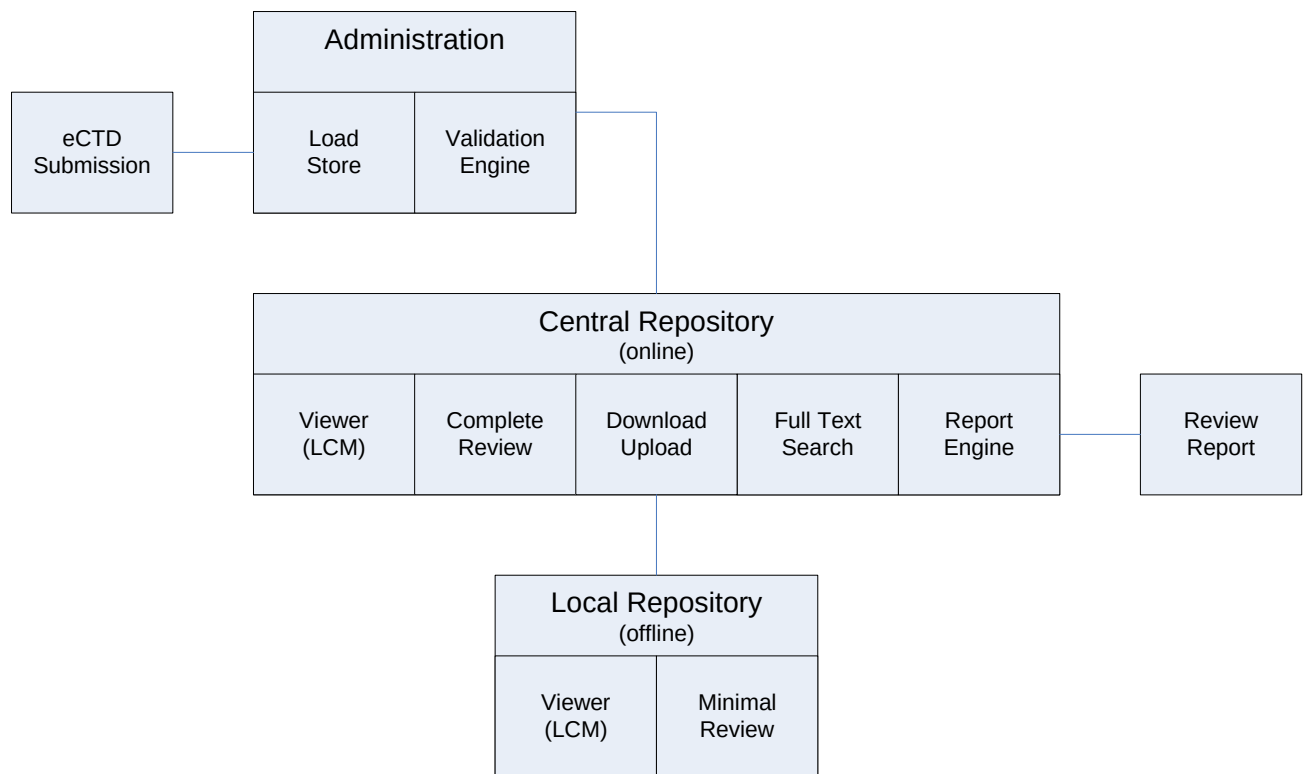
Functional Requirements

Along with compliance with eCTD and EU Module 1 standards and specifications, the EURS must fulfil a series of functionalities. These functionalities are described in the figure below and cover:

- Central and Local Repositories
 - The storage of information from eCTD submissions (according to Life Cycle Management operations) and from the review process (annotation etc) are stored in a unique central repository
 - Information from the Central Repository may be downloaded to Local Repository to support offline functionalities
- Functionalities related to the Administration
 - The loading of incoming eCTD submissions
 - The validation of incoming eCTD submissions
 - The reporting on the validation exercise
 - The subsequent loading of valid submissions
- Functionalities related to the View of eCTD submissions, (ability to see the information but make no changes) and
- Functionality related to the support of Life Cycle Management (LCM) of the product)
- Functionalities related to the Review of eCTD submissions (ability to view add annotations, etc)

General functional requirements are also provided to assure the EURS is a high quality, efficient and reliable system.

It is foreseen that the EURS system will evolve over time according to end-user requirements. This is covered in a section dedicated to "Standard Product-related Services". A probable evolution would be to have EURS instances (system and database) installed in some Member States, while others remain using the central EURS. The EURS system should be open to such hybrid architecture.



General Functional Requirements

The EURS must fulfil a series of general functional requirements, which cannot be categorised in one of the subsequent sections. Such general requirements cover:

- The organisation of information
- The multilingual support
- The configurability of the EURS
- The functionalities related to multi-users, profiles and privileges
- The logging capabilities of the EURS
- Etc.

ID	Requirement
GEN01	The EURS must support the organisation of eCTD submissions at least at the following levels: – At product level (i.e. the root level) that serves as the unique entry for a given pharmaceutical product for a given marketing authorisation holder; this level is identified by the application core number – At application level (i.e. the activity level) that corresponds to one procedure (e.g. initial marketing authorisation, variation IA, variation IB, variation II, renewal...); this level is identified by the application number (core number plus extension) – At submission level (i.e. the sequence level) that corresponds to one eCTD submission file; this level is identified by the sequence number The EURS should be open to support an additional organisational level for submissions, which could be based on the European Reference Product (ERP).
GEN02	The EURS interface must be provided in English, independently from the language used in the eCTD submission itself.
GEN03	The EURS may provide the interface in other European Union official languages, which is considered as an advantage.
GEN04	The EURS must provide configurability capabilities to individual users regarding such aspects as: – User attributes (default values when reviewing) – Naming and storage of personal data (e.g. search criteria...)
GEN05	The EURS must retain information on the current or most recent session. This is to allow the reviewer to go back to a previous status of his/her work on opening a new session
GEN06	The EURS must be a centralised system where multiple users access eCTD information simultaneously without interfering with each others' work.
GEN07	The EURS must identify the users working with the EURS. This can be supported by automatically retrieving user information from the operating system or network system. The system should function with the EMEA Oracle Internal Directory (OID). The EURS should be able to configure the authentication mechanism so that EURS systems installed at Member States premises (cf. possible hybrid architecture) could perform authentication against a local realm instead of the EMEA OID realm. In the case multiple authentication realms are in place, the EURS should support a single sign-on capability.

ID	Requirement
GEN08	The EURS does not require the limitation of access to functionality or to certain eCTD submissions. This means that every user has full access on all stored eCTD submissions. Although the EURS provides the concept of an Administration Tool, the related functionalities will not be restricted to a subset of users, and therefore there is no need to attach a profile to users.
GEN09	The EURS can be designed to run the system and the central repository on different machines but a link between the system and the central repository must be set via the intranet, extranet, or EudraNet (secure regulatory) network. The system should be Citrix/VPN compatible. In the case of hybrid architecture, the EURS system should be open to support the secure network (VPN of the Member State) to access the local application from outside the agency.
GEN10	The EURS must keep track of activities performed on stored data in separate log files (journal, audit trails).
GEN11	The following types of activities must be logged by the EURS: – Login – Logout Other manipulations can be logged (e.g. outcome of the review process)
GEN12	All information created by a reviewer using the EURS must be protected so that only logical deletion can be performed; this means that the related information is still physically present in the EURS but is not visible anymore. This feature must be accompanied by the opportunity to invert a delete by mistake by using a special dedicated function.
GEN13	The EURS must provide the functionality to manage the size of the central repository by archiving and restoring “older / out of usage” submissions.
GEN14	The EURS must provide full system administration functionalities that manage all the files needed for the good operation of the EURS (track size, clean up old versions...)
GEN15	The EURS must support the standard exchange mechanisms between software running on the same operating system. The most important mechanism to support is the copy/paste functionality between different running software programs (e.g. from EURS to MS Word). This functionality must be usable for the information from the eCTD submissions and from the review process.

Repository Requirements

The Central Repository is one of the main components of the EURS. It must store the eCTD information as received from the applicant as well as all the operations performed on the eCTD. This implies that many requirements on the Central Repository are indirectly defined by the operations to be supported on the eCTD. They are collected in this section.

Tenderers should be aware that a possible evolution of the EURS is to install systems in some Member States in the future. This would require the installation of a Local Repository next to the Central one, including synchronisation mechanisms.

ID	Requirement
CR01	The EURS must implement a Central Repository to store eCTD submissions and the outcome of the review process; the storage of these data must be open, portable and flexible.

ID	Requirement
CR02	The format of the outcome of the review process (annotations etc.) should be accessible outside the EURS (i.e. from other software such as office tools) and should support technological evolution (i.e. use of open formats such as XML).
CR03	The Central Repository must be accessible via an intranet, extranet, or EudraNet network connection.
CR04	The Central Repository must store all information about the eCTD submission as received without modifying it or allowing any modification, except when loading the eCTD submission into the Repository, where the application number could be filled at that time only.
CR05	The Central Repository must store all information about the outcome of the review process.
CR06	To support full text search capabilities, the Central Repository must be indexed.
CR07	The eCTD submissions that are stored in the Central Repository must be accessible to the reviewer using the standard explorer of the operating system, and allow the backbone XML file to be opened using tools other than the EURS itself.

Repository Download and Offline Features

The reviewer community can be very large and heterogeneous and therefore not all reviewers will have access to the Central Repository at all times to perform their work. The EURS must therefore support a disconnected work environment. This means that the EURS must support the making of a local copy of parts of the Central Repository. The EURS must make this local copy from the Central Repository to a Local Repository for offline process.

The EURS must put in place controls to avoid discrepancies between the information in the Central and Local Repositories:

- At a minimum, the EURS should download information from the submission (i.e. applicant data) and from the review process (i.e. reviewer data / annotations) for display only (i.e. read-only mode)
- It is preferred that the EURS supports the addition of review information into the Local Repository, to be copied to the Central Repository when back online. It is acceptable to limit the offline features to the addition of annotations, and to forbid the editing of existing review data.
- It is not mandatory but recommended to support the complete synchronisation of Central and Local Repositories (i.e. including the local editing of centrally stored information).

In any case, only the reviewer data (annotations) should be updatable when working offline.

Offline requirements are provided in the context of the Central Repository. In the case of possible hybrid architecture, offline features should be supported by the Local instance of the EURS system.

However, in the case of hybrid architecture, the needs for offline features may remain for end-users but in relation with the Local Repository, not with the Central Repository.

ID	Requirement
OFF01	The offline module of the EURS must be as light as possible to assure it can run on many environments (i.e. as many configurations as possible).
OFF02	The EURS must validate the client configuration (CPU, disk space, operating system...) against minimal requirements defined by the tenderer, before starting to install / download anything on the local machine regarding EURS. Download onto CD should not be possible. In the case of hybrid architecture, the EURS should be open to local backup systems.
OFF03	The EURS must support the download to the local machine of eCTD submissions, keeping intact the hierarchical structure of the submission: – Download of the XML files at the correct location – Preservation of the folder structure – Preservation of the file references (leaf nodes, node extensions...) The offline module must interact with the central EURS application using the authentication mechanism as defined in the EURS for end-users. There should be no possibility to download or upload information without authentication.
OFF04	The EURS must support the capability to download a complete eCTD submission as well as only a fragment of it. In case of fragment download, all the necessary files (XML fragment, referred files...) will be downloaded to the Local Repository for offline work.
OFF05	The EURS must support the capability to download fragments of one or more eCTD submissions to assure the offline work.
OFF06	The EURS must indicate the total size of information to download as well as the expected time needed to download, before performing the copy to the Local Repository.

ID	Requirement
OFF07	For a minimal version, the EURS should permit the limitation of the download to that of applicant data only (i.e. without reviewer data). Tenderers may provide additional control mechanisms for the download to a local machine but this limitation should at least be provided in the EURS.
OFF08	The preferred version covers the capability of the EURS to download applicant and reviewer data, and to support the creation of reviewer data offline. The newly created reviewer data will be copied to the Central Repository when back online.
OFF09	A complete synchronisation mechanism may be proposed between the Central and Local Repositories. Such a synchronisation system is not a mandatory requirement.
OFF10	The EURS must use a fast, transparent and reliable protocol to download information from Central to Local Repository, and to upload (if applicable) reviewer data from Local to Central Repository. The vendor should indicate the protocol used.
OFF10	In case of incident during the download / upload, it must be possible to resume the operation where it was stopped.
OFF11	Some parts of the repository can be downloaded by multiple users. As there is only local copy without modification (only new reviewer data to support), there will be no interference between those users.

Repository Extraction for Reporting

The outcome of the review process must be exported as a set of reports.

ID	Requirement
REP01	The EURS must support a series of predefined reports: – Export of all the review data introduced by all the reviewers for a given eCTD submission; this report must include public and private review data. – Other offered predefined reports can be listed
REP02	The EURS must assure that repository information (submission and reviewer data) is available to standard reporting tools like Business Objects, Crystal Reports or MicroStrategy. The vendor must indicate which standard tool(s) can be integrated and how the integration with the EURS is achieved.
REP03	The reporting tool must support the integration of information coming from other office tools (like replacement of certain parts in a text by a text processing tool, to produce “letters” with variable parts...).

Administration Requirements

The EURS must provide an administration tool that covers two main topics:

- The validation of incoming eCTD submissions
- The loading of valid eCTD submissions

Validation of eCTD Submissions

Before loading a new eCTD submission, the EURS must apply a series of validation rules. The outcome of this validation must lead to a validation report.

The validation rules are categorised in three main areas:

- Rules regarding the unambiguous compliance to ICH and EU standards and specifications; if such a rule is violated, an error must be reported. These are the core validation requirements.
- Rules that are specified in the ICH and EU standards and specifications, but which may lead to some interpretation; if such rule is violated, a warning must be reported.
- Rules that are not explicitly specified in the ICH and EU standards and specifications, but which it may be valuable to highlight. If such a rule is violated, that information must be reported.

If the validation is executed without errors the loading of the eCTD can start (next section).

There is no formal list of validation rules to be implemented in the EURS, except an ICH document on the "List of eCTD Validation Criteria" (Q&A 36).

ID	Requirement
VAL01	The EURS must allow the user to indicate the location of an eCTD submission to be processed (validation and loading) by browsing possible locations, e.g. file system (e.g. hard disk, removable media, CD-ROM, DVD-ROM...), internet address (using e.g. HTTP or FTP), document management system (using e.g. Documentum, Filenet), ... Possible locations where to load an eCTD submissions should be configurable so that an administrator can store a set of pre-defined locations.
VAL02	The EURS validation engine must be open, modular, flexible, user configurable and support: – Future evolutions of the ICH and EU standards and specifications; this must be achievable without endangering the complete validation engine (i.e. the validation engine itself must be stable). – Possibly to add local (i.e. national) preferences for validation defined by competent authorities and beyond the core requirements. Such configuration should use the following principles: ○ Clear separation between the validation engine and the validation rules ○ Possibility to define new validation rules using a logical notation ○ A validation rule must consist of following attributes: ▪ The range of the rule (EMEA, national, agency, personal). ▪ The severity of the rule (mandatory, warning, information). ▪ An indication of the time needed for the validation (elapsed time). ▪ The outcome of the validation (report provided). ○ The type of the rule (e.g. check for existence of a file at a location...).

ID	Requirement
VAL03	Validation is a time and computer-power consuming operation if applied to a large set of data. The EURS must provide features to overcome those inconveniences: – Provide the choice to perform the validation in background (with low priority without affecting foreground software). – Provide the choice to delay the validation (timed execution). – Provide the choice to activate a defined validation on a collection of submissions (batch mode). – Provide the capability to resume the validation after a crash without having to restart from the beginning (e.g. using traces in a log file). Unwanted interruption must give rise to the possibility to restart from the point of interruption. Specific attention must be given to the efficiency of execution (performance, elapsed time). An indication of the average time of execution must be provided for information (e.g. time of execution for a given size of submission).
VAL04	A warning should be provided to prevent duplicated validation of the same submission.
VAL05	The EURS must scan the complete eCTD, using all defined validation criteria as described in the ICH and EU-regional standards and specifications.
VAL06	eCTD submissions are exchanged according the Life Cycle Management principles (LCM). The way LCM is applied in eCTD submissions is determined by the applicant. It is of high importance that the EURS validates closely the LCM aspects of eCTD submissions. To achieve this, the validation engine must retrieve information from: – New submissions, as received from the applicant – Past submissions available in the Central Repository Some examples of validation rules specific to LCM: – In eCTD sequence "0000" (first submission), all the leaf elements must have an operation set to "new". – If the operation of a leaf element is set to "append", "replace" or "delete" (i.e. not "new"), the attribute "modified-file" must be set for that leaf, and make reference to an existing, previously submitted, file. – In eCTD submissions that are subsequent to "0000", the "related-sequence" field must be set and make reference to an existing eCTD submission; this means that all eCTD submissions, except the first one, must have a "related-sequence" set. To be able to use the EURS with submissions that do not start with sequence "0000" (e.g. product that has a past -submissions out of scope of the EURS), the user must be able to deactivate this specific validation rule. – Etc.
VAL07	The EURS must present a comprehensive, conclusive, unambiguous validation report including the following information: – Initial summary containing a clear validation status and the number of errors and warnings encountered. – List of errors and warnings, in order of criticality – Unambiguous reference to the validation rule for each error / warning shown. – Possibility to go from an error / warning of the validation report to the location in eCTD where the problem is located.

ID	Requirement
VAL08	The validation report must be stored automatically and kept as long as the submission is in the repository.
VAL09	If the validation process uses the repository to keep track of the validation, this process must, if (major) validation errors occur, clean up all traces in this repository.
VAL10	It should be possible to invoke the validation functionality multiple times

Loading of eCTD Submissions

If the outcome of the validation (cf. previous section) does not indicate major problems, the EURS must load the eCTD submission in the Central Repository.

The loading represents mainly the complete copy of the content of the eCTD submission, as delivered by the applicant, in the repository (storage facility) of the competent authority.

ID	Requirement
ADM01	The EURS must allow the integration of this step as a logical sequence of the previous step, not asking again for all the already available information.
ADM02	The EURS will check the required and available space in the repository before the starting the effective load.
ADM03	The EURS will calculate the estimated execution time needed to load the eCTD submission, notify the end user and visually indicate the progress to completion (not in case of batch / background processing).
ADM04	The EURS must display all the attributes of the envelope as specified in the EU Module 1 specification: – Initialized as populated by the applicant – With the possibility to change some values (e.g. the application number which is not always known to the applicant prior to first submission), but in such cases, the updated value(s) should be viewable within the eCTD but must be stored outside the eCTD – the eCTD is applicant data and as such immutable and only subject to comment. – With the possibility to add non-populated, optional values, but in such case, the updated value must be stored outside the eCTD
ADM05	The EURS must draw attention to some particular attributes like: – The application number, which is an essential part of the eCTD submission but not always available for the applicant when producing the eCTD. This must be handled with special attention. – The date when the submission is loaded, initialised by the system without possibility to manually update it.
ADM06	The EURS must validate the technical integrity of the loaded eCTD submission including: – The copy of folders and files as provided by the applicant – The verification (generation and comparison) of all MD5 checksums.
ADM07	The EURS must notify the end user about the outcome of the load operation.

View and LCM Requirements

The EURS focuses on the visualisation of the eCTD submission in all its aspects. To achieve this, the EURS needs a very user-friendly and powerful graphical user interface, including with full support of a pointing device (mouse). The EURS must provide the visualisation of all information available in the eCTD submission and allow manipulations as part of the reviewers' work.

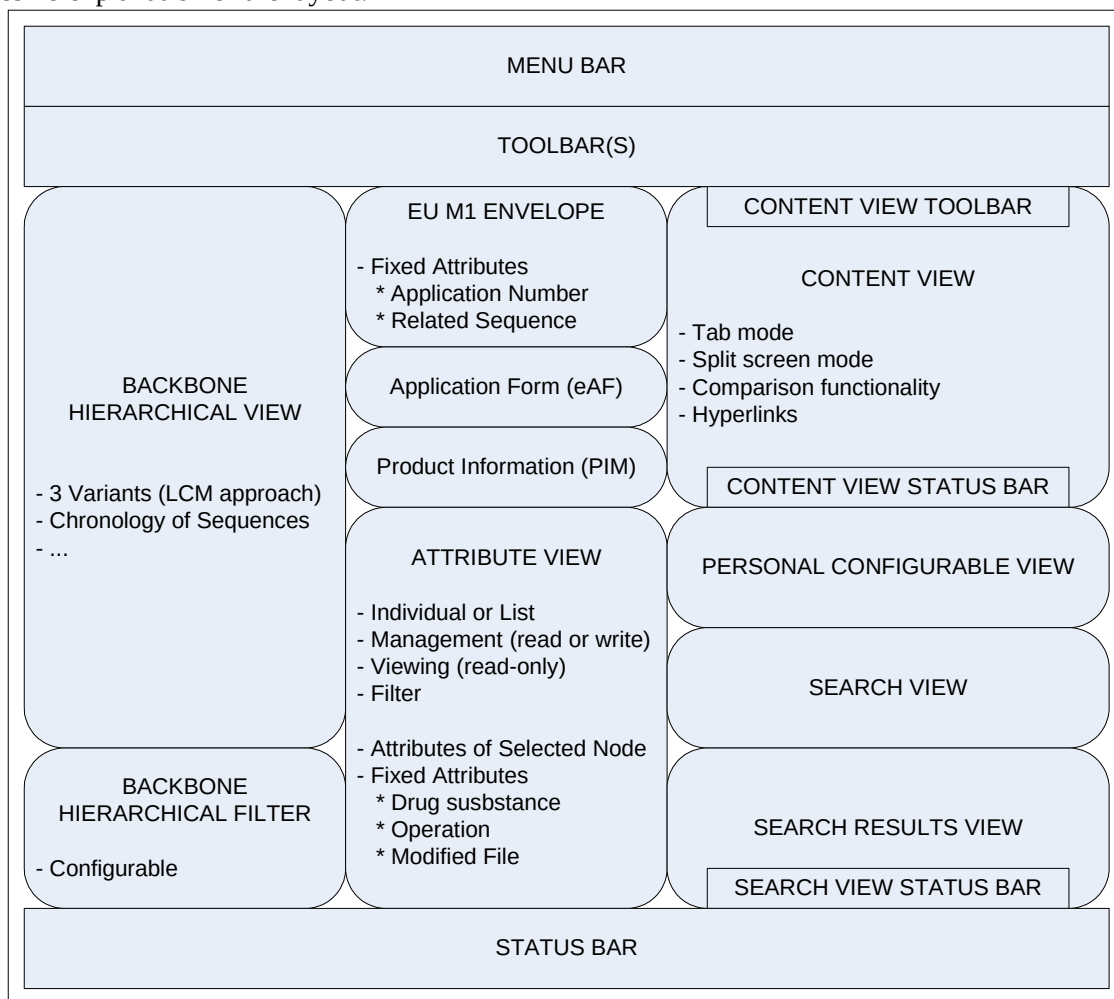
For the complex presentation of all aspects of eCTD submissions, the following principles must be supported:

- Desktop (workplace, window): complete graphical user interface with different zones for different purposes using MDI principle (Multiple Document Interface). This desktop must display the available information of the eCTD submission at one glance and to its maximum extent.

This desktop can be spread over different computer displays:

- Pane (view, section): one of the multiple specific zones serving a specific purpose and / or displaying a specific aspect of the eCTD.
- Desktop versus Pane: the desktop is a complex combination of multiple simultaneous panes. Any change in a pane must be directly reflected in all related panes (synchronisation).

The following block diagram gives an overview of the concept of desktop and panes. This diagram gives no explanation of the layout.



The requirements of this section focus on operations that do not encompass changes to the eCTD submission as it is stored in the repository, including:

- View, including:
 - Navigation through the complete submission by browsing through the hierarchical structure.
 - Viewing the content of individual elements and use of format-specific operations to browse and read the content.
- LCM, including
 - Support of multiple views of the product data taking into account the life cycle management capabilities provided by the eCTD
- Search and Filter the complete product, an application or a submission by using search or filter criteria.
- Print a selected portion of the product, application or submission on paper.

View Requirements

The EURS must present the full content of the eCTD submission in a comprehensible manner and support easy navigation and manipulation.

The support of features dedicated to life cycle management of eCTD submissions is described in the next section.

ID	Requirement
VR01	The EURS should support the capability to configure the display of the information, and to store such configuration settings as personal preferences. When the user logs in, his/her preferences should be used automatically.
VR02	The user interface of the EURS must be very intuitive, with focus on: – The graphical presentation ○ Use of graphical objects to present key aspects of the eCTD: ▪ Hierarchy with nodes and leaves ▪ Use of pictograms to represent eCTD content, such as the relation between sequences, leaf-attributes (e.g. operation)... ○ Use of contextual actions – The support of a pointing device (mouse) ○ Use of left button for selection, drag and drop ○ Use of right button for contextual action – The support of navigation ○ Use of navigational buttons (arrows, page up, page down, home, end...) and browsing through the hierarchy

ID	Requirement
VR03	The basic or standard layout of the desktop must have at least the following bars: – Top ○ One mandatory menu bar with all authorised actions for the user – Under the top menu bar ○ One or more toolbar(s) with the most frequent actions using pictograms – Bottom ○ One mandatory status bar with information about the user and its current context
VR04	Some panes are considered to be mandatory and will always be presented during the use of the EURS. Optional panes can be de-activated on the request of the user (to have a balance between amount of information and overload).
VR05	The EURS should allow personal configuration of the working environment by supporting some manipulations of bars and panes like relocation or resizing. The EURS must store these configurations as personal settings of the user.
VR06	The EURS must support the expansion of a particular pane to the size of the complete screen and back to its default size in the desktop.
VR07	The EURS must present a pane containing hierarchical information of the backbone for a selected eCTD submission. The following basic presentation (which can be customised, see separate requirement) must be provided: – The tree structure with relations between parents and children clearly identified with vertical and horizontal connectors – The node elements identified with the tag name – The leaf elements identified with the value of the attribute “title”
VR08	The EURS shall differentiate (e.g. using colours) the nodes that contain child nodes from the ones that are empty.
VR09	The EURS should support the capability to split panes.
VR10	The EURS must support the customisation of the presentation of the backbone view by allowing the display of additional attributes next to the basic identification of a node or a leaf. The EURS must support the display of the following additional attributes: – For a “product” node: the manufacturer, the invented name (from the envelope) – For an “application” node: the application number (from the envelope) – For a “submission” node: the sequence number (from the envelope) – For a “module” node, child nodes and node extensions: the name of the element – For a "leaf" node: the title of the referred document and the related LCM operation
VR11	The EURS must allow users to walk through the hierarchical structure, expanding and collapsing nodes to their lowest levels: – Expand / collapse the applications of a product – Expand / collapse the submission sequences for an application – Expand / collapse the modules for a submission sequence – Expand / collapse the nodes for a module to the detail of the leaf The EURS must support the collapse or expansion of all the sub levels of a given node in a single operation.

ID	Requirement
VR12	The EURS must provide a visual way to highlight the current position within the eCTD structure. This current position will be fully expanded from its position up to the root element.
VR13	The EURS must provide a pane at submission level with information from the envelope of the EU Module 1 containing all attributes (mandatory and optional, repeatable or not): – Application number – Applicant – Agency name – ATC code – Submission type – Procedure type – Invented name – INN – Sequence – Related sequence
VR14	If present, the EURS must provide a pane with application form information from the EU Module 1 (eAF). For the rendering, the EURS should make use of the eAF style-sheet.
VR15	If present, the EURS must provide a pane with product information from the EU Module 1 (PIM). For the rendering, the EURS should make use of the PIM Viewer.
VR16	The EURS must provide a pane with detailed information attached to a selected location in the backbone (node or leaf): information about (all available) attributes (i.e. drug substance name, drug substance manufacturer, product name, dosage form, product manufacturer, excipient and indication). The EURS should support customisation of the attributes to display as well as the order they are presented. The configuration must be stored as part of the settings of the user.
VR17	The EURS must provide a pane with the content and details of one or more selected documents. The EURS must support all file formats as defined in ICH and EU-regional standards and specifications.
VR18	The EURS must support the view of a selected document without allowing any changes (i.e. it is not allowed to change the original eCTD submission). Some features of this “view” functionality should be provided as menus and toolbars: – Toolbar(s) with buttons for the most important operations, e.g. scroll through the document – Status bar with information about the total number of pages of the document and the actual page.
VR19	The EURS should support the view of file formats that do not comply with ICH and EU standards and specifications (but it should be reported that these files are present in the validation, and the files identified).

ID	Requirement
VR20	The EURS must support the capacity to open several documents simultaneously. If multiple documents are simultaneously open, the EURS should support the following capabilities: ○ Tabbing: If the documents have the same file extension, a single pane should display with the different documents in a dedicated tab (to avoid the repetition of the same menus and toolbars). Clicking on the tab brings another document in the foreground. ○ Splitting: If the documents have different file extensions, every document will have its proper pane with dedicated menus and toolbars. As all information in the different panes is linked (see requirement on synchronisation of panes), the EURS will not use a SDI (single document interface).
VR21	The EURS must provide a comparison function where the details of 2 selected documents are put side by side at the same location in the document (i.e. moving them together). A visual display (highlight, different colours) should emphasis the differences between the displayed documents.
VR22	The EURS must support the use of hyperlinks in documents and support the redirection to other places in the same document or to places in other documents.
VR23	The EURS must allow the viewing of simple structured (but non eCTD) electronic submissions

LCM Requirements

The EURS must exploit the knowledge of the lifecycle to its full extent, meaning relations between sequences must be visualised in an intelligent and comprehensible manner. To achieve this, the EURS must take into account two important concepts:

- The access to submissions through the application it belongs to (Application Level)
- The views to provide to reviewers to ease the identification of changes (Submission Level)

Application Level

The display of the eCTD submissions must be categorised by application. For a given product, many regulatory events may occur and these happen in the context of an application (initial marketing authorisation, variation, renewal...). The display of an eCTD sequence must always be provided in the context of the particular application it belongs to (determined by unique application number).

Submission Level

The EURS must exploit the knowledge of the lifecycle to its full extent. In order to facilitate the review, the following variants must be supported:

- Sequence View (SV)

This is a basic and simple view with focus on a single eCTD submission. This view should provide the following features:

- Display of the backbone hierarchy using a tree structure with nodes and leaves
- Display of attributes related to nodes and leaves, with possibility to view the files referred from the leaf elements

- Current View (CV)

This is a complex cumulative view with focus on a sequence of eCTD submissions and interpretation of life cycle management operations. This view should provide the following features:

- The selection of an eCTD sequence number to use as the starting point
- The interpretation of attributes of the envelope (i.e. related sequence) and the leaf attributes (i.e. operation and modified file)
- The compilation of the sequences from the selected one, back to the first one.
- The display of the compiled information using a tree-structure with nodes and leaves. This view cumulates all the nodes and leaves of the selected sequence plus all the related previous sequences, in order to display the information valid at the time of the selected submission. This view should also provide capability to trace the life cycle management operation from submission to submission (e.g. to provide information on replacing and replaced files)
- This corresponds to the visualisation of all sequenced "index.xml" files with interpretation of the leaf operation attribute
- Where each 'current' leaf is displayed, an indication of the sequence in which this leaf was submitted and the submission type this sequence referred to should be presented

- Cumulative View (TV)

This is a simple cumulative view with focus on the sequence of all eCTD submissions organised simply by sequence. This view should provide the following features:

- The display of the cumulative information using a tree structure with nodes and leaves from all submissions starting from 0000
- The display of a sequence view per sequence.

– Past Sequences View (PSV)

This is a simple view of the past submissions with focus on:

- The display of past sequences, ordered using the related sequence attribute of the envelope

View across the sequences at the level of a single leaf

– Application/Activity View (AV)

The eCTD lifecycle management is made up of a number of individual regulatory activities. An individual activity is something that may modify the approved set of data for a drug - this may be a new variation, submission of a PSUR or a licence renewal.

An activity is represented by one or more individual eCTD sequences which may be non-consecutive

The application/activity view is a complex view of all current information relating to a particular set of submissions/sequences that are linked by the same application number (with suffix) e.g. a particular variation, line extension. These submissions/sequences may not have been submitted sequentially, but it should be possible to extract and compile them to provide a set of current information relating to a particular procedure.

ID	Requirement
LCM01	The EURS must support the categorisation of eCTD sequences by application.
LCM02	The EURS must display eCTD information using at least one of the following possible variants (see above): – Sequence View (SV) – Current View (CV) – Cumulative View (TV) – Past Sequences View (PSV) – Activity View (AV) The primary panes are the Current View (CV), which enables the user to address the current state of a submission as a whole and the Activity View (AV) (e.g. New Application, Line Extension, Type II Variation) for a particular product by building a snapshot of all submissions (even if not sequential) related to the particular submission type.
LCM03	The EURS must enable the navigation through sequences by clicking on a past sequence number of a given leaf to open the details of that document in a selected sequence in the past.

ID	Requirement
LCM04	The EURS must provide on user request content information about all past related sequences attached to a given application number. The EURS should support the capability to limit the query in the past to a certain number of sequences. This pane should allow the user to have a clear view of related submissions per application with the capacity to navigate from a selected submission to the initial one.
LCM05	The EURS must provide envelope information about all past related sequences attached to a given application number, on user request

Search and Filter Requirements

The EURS must provide help to the reviewer by supporting the search for specific elements in eCTD submissions. Although the eCTD submission is a mixture of structured (nodes, attributes and values) and unstructured (free text and files) information the EURS must provide an integrated search interface, and support the search on all kinds of information.

Search functionality should use the following concepts:

- Scope
Identification of the location where the search applies
- Search formulation
Support of two types of search elements:
 - Combination of attribute and value (structured)
 - Free text (unstructured)
- Results
List of matching elements, optionally with the possibility to
 - Add / delete columns in result list
 - Indicate a matching score
 - Invert the order of result list

ID	Requirement
SFR01	The EURS must support the restriction of content panes according to the results of search filters.
SFR02	The EURS must provide a pane where the user can formulate a search with two variants: – Predefined simple search formulation – User-defined complex search formulation Simple search formulation should be the default option but the EURS must provide a navigation element (e.g. button) to go to the complex search.
SFR03	The EURS must provide the following predefined simple search formulations: – The search on major attributes of the XML files (at envelope, node and leaf levels) – The full text search inside documents (inc. bibliographies, table data...); the full text search capabilities of the EURS must support at least PDF, RTF and Ms Word file formats

ID	Requirement
SFR04	The EURS must provide user-defined complex search formulations (i.e. configurable) where the user can add criteria of preference: – Search on specific XML attributes from envelope, node or leaf – Search on reviewer data (e.g. annotation, received date, application status) – Full text search inside all documents (bibliographies, table data, ...) These criteria can be put together using Boolean and comparison operators.
SFR05	Every search formulation should support the use of wildcards.
SFR06	The EURS must support the search in physical folders and files using their definition in the XML backbone (e.g. xlink:href="m2/22-intro/introduction.pdf"). This can be provided by using pseudo attributes such as: – folder = m2/22-intro – file = introduction – file-extension = pdf The EURS must construct the effective search criteria from these pseudo attributes. There is no intention to do a direct search on the physical file system.
SFR07	The EURS must support the storage and management of the configurable search formulations so that they can be reused afterwards. The following features should be supported: – Locate where to store the search formulation (e.g. in personal settings) – Save a search formulation using a user defined name – Choose one search formulation to use as default – List all the stored search formulations – Open a selected search formulation for re-execution – Delete a selected search formulation
SFR08	The EURS must support the execution of a search simultaneously on: – eCTD XML files (envelope, backbone, Module 1...) – Reviewer data (see section on review requirements) – Files referred from leaf elements, supporting different formats (XML, PDF...), which means that the structured XML files are also used in the unstructured search. The Central Repository containing all eCTD submissions must therefore be indexed by an indexing service (requirement on repository). There is no intention to do a direct search on the physical file system.

ID	Requirement
SFR09	The EURS must provide a pane where the search results are listed with following attributes: – Matching documents, nodes and leaves – Display of key attributes, like: ○ The document title (from the leaf element) ○ The file name of a document ○ The LCM operation ○ ... This pane must also have a status bar to indicate the total numbers of matching elements found by the search. This result pane must allow to: – Open a selected document out of the list – Sort using attribute values (e.g. title) – Filter using attribute values
SFR10	The EURS should support the filtering of the hierarchy by applying certain values to certain attributes (e.g. application level application number EMEA/H/C/xxxxx/II/* will give only submissions that are related to the VAR II of product...).

Print Requirements

The EURS must allow users to select and print documents either individually or in batch mode. Before printing, users will be provided with information on the selected documents to facilitate the printing process, e.g. on the size of the compiled document, the number of documents...

Printing functionality should rely on the following concepts:

- Selection of information to print
 - Documents referred from a node or a list of nodes (i.e. including all the documents referred from the leaves that belong to the selected nodes)
 - Documents referred from a leaf or a list of leaves
 - Possibility to restrict documents to a given extension or to specify some attribute values (e.g. for a given substance, only new files...)
 - Print documents individually or compiled together into a report
- Printing operation
 - Preferably accompanied with the possibility to cancel printing
 - View the file size, the number of pages and the list of documents to be printed.
- Spooling operation
 - The option to select another print queue
- Printing execution
 - The delivery on paper remains outside of the EURS and provided by the operating system

ID	Requirement
PR01	The EURS must support the printing of: – The whole or portions of the eCTD submission, using the format as provided, and relying on the related native program (e.g. Adobe). The documents will be printed in the sequence as they appear in the backbone. – Most of the files can be expected to be in PDF format – Worldwide (ICH) and regional standards using XML must be printable according to their specifications – Vendors must indicate if additional formats are supported ○ Additional XML files should be rendered through XSL style-sheet(s) ○ Ms Word documents ○ ... – Vendors must indicate if other information can be printed ○ Combination of information from the backbone and from the review process ○ Combination of ▪ Backbone information ▪ Document content ▪ Review process ▪ ...
PR02	The EURS must support the printing of documents from different panes: – Pane providing the hierarchical view of the backbone In case the variant Current View (CV) is activated, the EURS must use this compiled information to assemble all valid documents according to the life cycle management. – Pane providing the search results The user must be able to choose if he/she wants to integrate hyperlinks (the EURS will alert the user if hyperlinks exist). If yes, document with hyperlinks will cause the hyperlinked documents to be printed directly after the original document in the order as they appear in the original document (without repetition if the same hyperlinked document appears more than once). This feature needs to be limited to one level, so that hyperlinks in hyperlinked documents will not be treated. <u>Example:</u> The user selects document A to print. Document A has internal links to external documents B and C. Document B has a link to external document D. The EURS will provide the option to print document B and C at the same time as A, but not document D.
PR03	All the documents selected must be compiled into a single overall document (called a report) using the order as defined in the backbone. If such report is part of the predefined reports of the EURS, it must be detailed. There is no requirement to add an overall page numbering or header / footer to the report.

ID	Requirement
PR04	The EURS must store the compiled document (see above) into a (temporary) PDF file. This means that if a mixture of file is selected, the EURS will reformat them into a single uniform PDF file (e.g. XML and Ms Word documents need to be converted). If for legibility reasons, a native format is preferred to PDF, tenderer should highlight it in the EURS proposal. The EURS will use the content-view pane to display the compiled document. The user will be allowed to check if content and format are as required before an effective print. The status bar of the content-view pane will indicate the file size and the number of pages of the compiled document, to give indication about the volume effectively sent to the printer. In any cases, there will be a single file spooled to avoid mixture with other print jobs.
PR05	The EURS must support to choose a printer attached to the computer of the user where the output on paper will be produced (spooling).
PR06	The EURS must support to print a specific report called “Table of contents” of the backbone. This report must clearly indicate the hierarchy of the submission (display of tag names with indentation and vertical lines) and only display the “title” attribute of the leaf elements.
PR07	The EURS must be able to print a specific report based on a collection of non-continuous elements using for instance one of the following features: – Drag and drop of elements into a "print pane" – Re-order elements in this "print pane" – ... The “print pane” as described above can be used for this purpose any other similar feature can be created.
PR08	The EURS must be able to print a specific item based on the content of the "print pane".

Review Requirements

In general, requirements described in this section must be only implemented on the Central Repository. Downloaded parts from the Central Repository to the Local Repository should be read-only with the exception of adding annotations (optional, but preferred; see section – Repository Download and Offline Features).

The EURS must allow the reviewer to capture the outcome of his/her review work on the eCTD submission; this is called reviewer data. Reviewer data applies to an eCTD submission, and more especially to the location of an element in the eCTD submission. This reviewer data must not change or compromise the integrity of the eCTD submission.

Reviewer data is personal and must be attached to the concerned reviewer (only the author can manage his/her own reviewer data), but reviewer data can be opened for consultation by any other EURS user.

This reviewer data can be categorised as follows:

- Content: reviewer data with effective content (e.g. annotation, review...)
- Progress: information about the progress of the review (e.g. tracking of the progress of the review, identification of the portions of the submission that have been reviewed...)

In any case, the reviewer data must be connected to a location (module, node, leaf...) of the eCTD submission, and therefore to a given file where applicable.

ID	Requirement
REV01	The EURS must have a standard capability to add reviewer data, either as: – Effective review content (e.g. annotation, review...) – Progress information (e.g. progress status, tracking...)
REV02	The EURS must store the two following types of information related to reviewer data: – Control ○ Connection of the reviewer data to an eCTD element (e.g. node) ○ Provide a unique identifier for the reviewer data ○ Author of the reviewer data ○ Timestamp of the creation of the reviewer data ○ For tracking information, the status ○ The capability to define a hyperlink connected to an object ○ The capability to provide a title or name (for hyperlinks) ○ The visibility of the reviewer data (e.g. personal vs. common) ▪ If set to "personal", data is not visible for other users ▪ If set to "common", data is visible to every user, but can only be managed by the author ○ The maturity of the reviewer data (e.g. work vs. final) ▪ If set to "work", data is intended for the author only ▪ If set to "final", data is intended to be included in the reporting of the review process. – Content ○ Structured (i.e. meta-data or attributes), which can be: ▪ Predefined, as part of the EURS ▪ User-defined, stored in the user settings ○ Unstructured, using reference to an attachment (linked object)
REV03	The connection between the eCTD submission element (backbone location) and the reviewer data makes part of the reviewer data (see control aspect in previous requirement). The connection can be set to a node, a leaf or a specific location inside a document. The EURS must support the attachment of reviewer data to any level of the eCTD submission: – Product node (i.e. root level) – Application node (i.e. linked to a regulatory procedure) – Submission node (i.e. linked to a sequence) – Module nodes and child nodes (including node extensions) – Leaf nodes – Document as a whole – Precise location inside a document – A range inside a document (e.g. from page x to y, section z...) This reviewer data is part of the EURS, and not part of the tool that would be used to capture the review data for a specific file format (e.g. PDF). The reviewer data will not change or compromise the integrity of the eCTD submission.

ID	Requirement
REV04	The EURS must be able to provide an integrated view of all reviewer data independently from the way the user created them or the way the EURS stores them.
REV05	The EURS must support an unlimited number of reviewer data (content and progress) attached to a given eCTD element. The EURS must support the concurrent review of the same eCTD fragments by different reviewers.
REV06	Reviewer data about progress should have the following restrictions: – There should be only one progress information per eCTD element. – There should a user restriction on who can add such progress information The EURS shall provide means to help the reviewer to track the progress of his/her work. But it is the responsibility of the reviewer to add progress information; i.e. it is not expected that the EURS provide such information automatically
REV07	The EURS must use the hierarchical pane and eventually the content pane to determine the eCTD elements (node, leaf, document...) where to attach a review. Details about the reviewer data should be filled from the attribute pane.
REV08	The EURS must use the hierarchical pane and eventually the content pane to determine the eCTD elements (nodes, leaf, document...) where to consult a review. Details about the reviewer data should be displayed in the attribute pane.
REV09	A user can only consult reviewer data that he/she created and all the ones that have been defined as “common”.
REV10	A user can only consult updated reviewer data that he/she created, except when working offline (see section Repository Download and Offline Features).
REV11	The EURS must support filter capabilities to limit the number of lines in the reviewer data list (e.g. do not present all the reviewer data which are common...).
REV12	The EURS must support the attachment of reviewer data referring to files. The EURS should support the following file formats: – All the file formats specified in ICH and EU specifications must be supported – Other file formats may be supported as well The EURS can limit the support of file formats that are not defined in the ICH and EU standards and specifications when creating an attachment. The view or updated of these file formats can be handled outside EURS using related programs accessible on the workstation of the reviewer. The EURS must use the content pane to display attachments (for file formats supported by ICH and EU standards and specifications).
REV13	The EURS must clearly indicate in the hierarchical pane and eventually in the content pane the presence of reviewer data (i.e. highlight, different colour, special pictogram...).
REV14	The EURS should be able to use some reviewer data as a basis for a filter.
REV15	The EURS must use reviewer data of type "progress" to facilitate the communication between different persons involved in the reviewing process. This could be used as a kind of workflow to inform certain persons / groups about their involvement in the review process. This may require a separate workflow engine to direct and control actions on the eCTD.

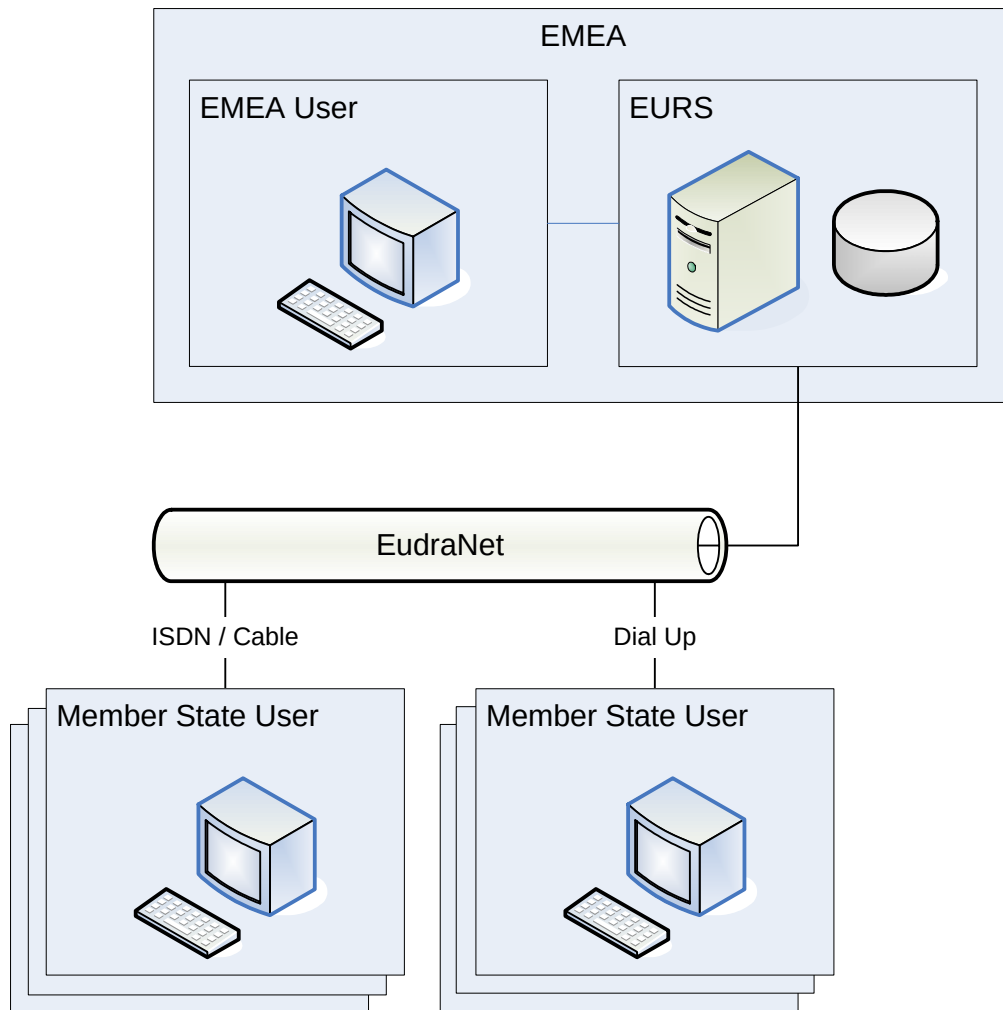
ID	Requirement
REV16	The EURS must support to enter the date of the end of review process. When the review process is closed for a given submission, the EURS should forbid the addition and edition of reviewer data.
REV17	The EURS must support the management (add, edit, delete) of reviewer data until an eCTD application is marketed (initial MAA). At this point in time this submission and all related submissions (in the past) will become frozen: the EURS must forbid the management (add, edit, delete) of any reviewer data attached to one of these submissions.
REV18	The EURS must support the definition of checklists. The EURS must provide the capability to compare a checklist against reviewer data of type progress (e.g. to assure that all the elements of the checklist have been covered by a reviewer).
REV19	The EURS must provide a functionality that supports the management of eCTD elements into a personal workspace (i.e. scrapbook).
REV20	The EURS must provide a pane with two parts: – List of links in your personal workspace – Details about the links as retrieved by the EURS from the eCTD submission.

Non-Functional Requirements

The EURS is intended to run in the context of a centralised architecture. The storage (central repository) and application layers will be hosted at the EMEA premises, and accessed from Member States using a secure network or similar.

Due to the involvement of a large number of Member States, the EURS should work using a minimal infrastructure, in terms of hardware (at user premises) and network (e.g. single machine using a dial-up connection).

The figure below provides a description of the context where the EURS should operate.



As stated in the figure above, some Members States may be connected to EudraNet through a dial up connection. The EURS should take into account such kind of connection in their architecture and design. To cope with such connection capabilities, the EURS may provide an alternate solution that would consist in a decentralisation of the application and/or the database (even in a connected mode). Such a hybrid architecture (including application and/or repository at Member State premises) should be clearly explained by the vendor.

Technical Architecture

General Infrastructure Requirements

The EURS must be able to run on as many platforms as possible without complex operations for installation. Preference is given to an infrastructure relying on open standards.

ID	Requirement
GI01	The technical architecture of the EURS must be modularised to isolate at least following components: – A Central Repository – An Administration Tool to validate and load the eCTDs in the Central Repository – A Review Tool to navigate, open submissions, search information and add reviewer data (annotations) either: ○ Online (stored in the Central Repository) ○ Offline (stored in the Local Repository)
GI02	The minimal requirements needed to run each of the components stated above (Central Repository, Administration Tool, and Reviewer Tool) must be clearly defined.
GI03	The EURS must be deployed in many different locations, in many different environments. Preference is given to architectures that are as independent as possible of any special hardware and software configurations.
GI04	The architecture of the EURS must be flexible and open enough to allow evolutions according to new requirements.
GI05	The vendor must indicate if there are any specific technical limitations imposed by the chosen architecture.

Infrastructure Requirements for the Central Repository

The architecture of the EURS should consist of a central application accessed over a secure network (EudraNet) that stores information into a central repository.

This "central" architecture may have drawbacks in terms of performance, and a hybrid solution may be proposed with appropriate explanation and justification. A hybrid solution could propose the installation of an application locally to resolve potential connection issues (e.g. limitation of bandwidth).

ID	Requirement
ICR01	The Central Repository should support at least 250 eCTD submissions of average size (2 Gigabytes).
ICR02	If a "decentralised" architecture is proposed, the choice for such approach must be clearly explained.
ICR03	Reviewer data must be stored in a structured, portable and non-proprietary format (e.g. XML).
ICR04	The Central Repository should be scalable and extensible.
ICR05	The Central Repository must support complex search operations (see requirements on search functionalities). Search operations must be handled efficiently: search results must be presented in less than 10 seconds.

ID	Requirement
ICR06	The size or usage of the repository cannot have an impact on the performance: – The growth of the repository by constantly adding new eCTD submissions should not impact the performance of the EURS – The connections of 500 concurrent users should not impact the performance of the EURS – Complex validations and load operations should not impact the performance of the EURS
ICR07	The vendor must indicate the approximate time needed to validate and load a first sequence submission (complete) using the minimal requirements as described earlier. This value should be based on a first eCTD submission of average size (2 Gigabytes).

Infrastructure Requirements for the Administration and Review Tools

The Administration and Review Tools are key components of the EURS. The vendor should propose and justify the choice of architecture for these components (e.g. rich client, thin client, web interface...)

ID	Requirement
IAR01	The Review Tool must be user-friendly, powerful and fast. It must implement all graphical features
IAR02	The vendor must document the reasons for the selection of the architecture for the Administration and Review Tools.

Software Product

The EURS must be packaged as any professional software product. The provided package must support a wide range of platforms, with easy installation and usage.
The evolution of the product is described in a separate section on software maintenance services.

ID	Requirement
SP01	The EURS product must indicate the supported platforms.
SP02	The vendor must indicate if the EURS is packaged in product modules (e.g. separated packages for the Administrator Tool and for the Review Tool” or if it is provided as a whole package.
SP03	The EURS can use other (e.g. native) software to: – Navigate and search into folders (e.g. Ms Windows Explorer) – Index and perform full text searches (e.g. Ms Windows Indexing Service) – Navigate in files (e.g. Adobe Acrobat Reader) – Search into files (e.g. Adobe Acrobat Reader) – Annotate in files (e.g. Adobe Acrobat) – Use meta-data (DMS)
SP04	Native software, if any, must be packaged and licensed together with the EURS product and be installed as part of the EURS (including the check if already installed).
SP05	Native software, if any, must be executed as part of the EURS, and not as a separate software or process.

ID	Requirement
SP06	Native software, if any, must provide functionality as part of the EURS through new menu entries or toolbars in the EURS desktop.
SP07	Native software, if any, cannot be used to create data: native software must always access data in a view / read-only mode. An exception can be made if the data created by the native software is stored in the EURS Central Repository, together with other reviewer data. Reviewer data can only exist at the level of the Central Repository. Isolated data are not allowed (e.g. Adobe Acrobat annotations are only allowed if they are stored in the central repository together with other reviewer data; annotations cannot be stored as part of the PDF files).
SP08	Installation and configuration are part of the product (all versions and all components): the EURS must be installed / configured out of the box through a wizard-like approach. The installation / configuration must end with a detailed outcome report.
SP09	Special settings for installation or configuration must be as much as possible avoided (not to endanger other software installed on the same systems, or the system itself). If they are needed, they must be clearly indicated and described with their possible impact.
SP10	The usage of the EURS product must be assisted by a detailed, intuitive and intelligent online help system, including: – Description of main functionalities in a tutorial – Context sensitive help on chosen action – Indexed search topics – User defined search
SP11	The EURS product must be accompanied by a complete and detailed documentation set, consisting of: – A user manual for the Administration Tool component – A user manual for the Reviewer Tool component – An administrator manual containing ○ Description of the architecture (inventory and description of components) ○ Installation manual ○ Operation manual (especially for the Central Repository component), including backup / restore procedures At least 1 paper copy of the documentation set must be provided with the EURS product.
SP12	The vendor must support the previous versions of the EURS: at any time, the vendor shall support the current major release, the previous major release, and all the maintenance releases that have been issued since the release of the major release before the current version.
SP12	The support must be handled as part of software maintenance services (see separate section).
SP13	The support must be protected by an escrow agreement.

Standard Product-related Services

Operations and Support Services

The EURS will be installed on a number of sites (up to 33 sites). The sites where the EURS will be installed, and their users, must be supported on a daily basis. Such operational support covers the help in installing the EURS on the site and using it, without changing the EURS. No bug correction or new feature implementation is covered in this section; this is treated in the next section about software maintenance services.

The vendor must set up a specific organisation to support the sites where the EURS is installed, with the following elements:

Computer Support

This covers the support that does not need a human interaction:

- Provide database knowledge about all potential issues of the usage of the EURS, to enable the user to solve issues he/she may encounter. If these issues imply maintenance, then supplementary information must be presented about
 - The planning when a solution will be provided (cf. maintenance section)
 - The identification of the release (version number) where the issue is resolved
- Provide, manage and feed Frequently Asked Questions (FAQ)
- Support a EURS Community where the EURS vendor and EURS users may exchange insights, solve problems and share ideas

Human Support

This covers the support that needs a human and personalised action from vendor:

- The vendor must provide information about
 - The human support provided
 - The organisation structure put in place (e.g. one or more levels depending on the complexity of the issue)
 - The procedure put in place (e.g. escalation levels)
 - The provided services
- The vendor must cover the following channels for the support:
 - Telephone assistance
A telephone number for the vendor support shall be provided. Any user from the site where the EURS is installed shall be entitled to contact the support line (using one unique telephone number) in accordance with the service levels set out below. Technician support shall be available such that any problem that can be solved via the telephone is solved immediately during the phone call.
 - Electronic mail assistance
A unique e-mail address for product support shall be provided. Responses by the vendor should conform to the service levels set out below. Problem resolution shall be provided by e-mail or telephone to the extent that this is possible.
 - On-site support (field support request)

When a problem cannot be resolved through telephone or e-mail communication, the vendor shall dispatch a technician to the site where the problem is occurring, and rectify the problem.

The vendor must provide information about the operations usage (monitoring compliance, collecting and analysing performance data...), the areas where problems occur, and continually refine the services offered.

This support organisation is also responsible as front-office for the problem reporting about the EURS product. Software anomalies and software change requests (i.e. request for a new feature) will be transferred to the “software maintenance services” (see next section).

The vendor shall operate the support during the normal hours of service of the countries of the European Union:

- From 08:00 to 19:00 CET
- From Monday to Friday.

Service levels and target requirements:

Priority	Response Target during hours of service	Resolution Target during hours of service	Example	Yearly Target
-	1 day	-	User guidance	99% within target

Software Maintenance Services

The EURS shall have 2 major sources for maintenance:

- The vendor
Maintenance can be initiated by the vendor to keep the EURS aligned to the latest ICH and EU-regional standards and specifications. This will lead to functional and technological developments: e.g. upgrades to ensure compatibility with new releases of the technology stack, such as database and operating system.
- The EURS users
Maintenance can be initiated by the EURS users as they may propose future evolutions of the EURS. In most of the cases, these evolutions are expected to be of general interest: the request will impact the EURS installed on each site. However, every site may have personal requests for evolution that are only relevant for their site.

The maintenance can be divided into:

- Corrections (bugs)
- Perfections / improvements of the EURS without changing the functionalities. Such improvements are foreseen to prevent failures and / or optimise the software. This might be done, for example, by modifying the components that have the highest failure rate, or components whose performance can be cost-effectively improved.
- Adaptations / evolutions of the EURS including new functional features / requirements. Adaptive maintenance may be needed because of changes in the user requirements, changes in the target platform, or changes in external interfaces.

The vendor must set up a specific organisation to support the requests coming from a site where the EURS is installed. Such organisation should support the following procedures:

- Fast procedure based on quick and effective problem resolution to minimize downtime:
 - Corrective maintenance (mostly bugs that block the usage of the EURS) will always be handled with high priority, no decision workflow, immediate software update and release preparation (patch).
Users shall be entitled to submit requests to the vendor, identifying potential errors in the software. Such requests should be done in writing and provided to the vendor with sufficient information to reproduce the error; the request should be transmitted to the vendor by defined channel using a defined support address.
- Formal procedure based on a software review committee (vendor and site representatives) who meet on a periodical basis to discuss content and timing of evolution of software:
 - Capture of new requests, together with operations / support services (see previous section).
 - Analyse, prioritise and decide on open requests (periodically by a review committee)
In case of a personal request from a specific site, the review committee will make the decision whether the request is of general interest or not, and therefore if it will impact all the sites.
 - Implement approved requests.

In consideration of the size and diversity of the sites where the EURS is installed, special attention must be given to following requirements about software changes (correction, evolution):

- Every change must be tested, with emphasis on integration and non-regression testing.
- The deployment of a change must be supported by a release procedure:
 - Define the content and the timing of a software release according to the needs of the users. This means that:
 - Solutions to urgent problems are released as soon as possible only to the people experiencing the problem, or who are likely to experience the problem
 - Other changes are released when the users are ready to accommodate them
 - Every software release must be accompanied by a Software Release Note (SRN). The Software Release Notes shall describe:
 - The software item title or name
 - The software item version or release number (the structure of the version number should reflect the number of different types of releases used)
 - The changes provided in the release
 - The list of configuration items included in the release
 - The installation instructions
 - The description of the issues resolved (using the unique identifier of the issue that was used when brought up)
 - The release must be prepared specially for the target site(s), as some requests may be limited to certain sites only:
 - By putting the release on media and distributing it (push-strategy)
 - By working via an update site that is periodically checked by EURS (pull-strategy)
 - The install release shall use an automatic installation procedure that can be run by a user or a technical administrator.

The installation process should be reversible and should assure that rollback to the state before the installation process was started is always possible. One way to do this is to make a backup copy of the existing system before starting the installation.

If a change involves a modification in the structure of the Central Repository (i.e. amend the structure of the reviewer data), an extra procedure must be provided to migrate all existing data into the modified structure of the Central Repository.

Service levels and target requirements:

Priority	Response Target during hours of service	Resolution Target during hours of service	Example	Yearly Target
Emergency	30 minutes	4 hours	Whole or critical part of the EURS are unusable	80% within target
High	1 hour	8 hours	Important, but not immediately critical, parts of the EURS are unusable	85% within target
Normal	2 hours	2 days	Other inconvenient or non-urgent problem	99% within target

Additional Services (Training)

The vendor must provide training services at the sites where the EURS is installed, in using the EURS. Training must be organised for following user profiles:

- Reviewer
- Submission administrator (validation and loading)
- Technical administrator

Training will be done at the premises where the EURS is installed (in-house training) using the infrastructure of the site.

Annexes

- I Costing Sheet to be used by Tenderers
- II Exclusion criteria statement and detail of supporting documentation required
- III Summary Checklist of Documents which Tenderers must submit
- IV Draft contract

ANNEX I – COSTING SHEET

Tenderers must use a table similar to that below to submit their tender. **Tenderers should submit this table in separate binders or folders which must be clearly labelled.**

The data included in the table is by way of example. It is intended only to illustrate the principles to be followed in completing the table. Neither the numbers of days, nor the daily rates are to taken as representative of any expectation on the part of the EMEA. The formal deliverables must be shown in the context of the appropriate phase of the contract. Prices should be quoted in Euro, net of VAT.

NAME OF TENDERER: _____

Formal deliverables	Resource Profile	No. of resource units	Total No. of days	Daily rate (in €)	Total (in €)
<i>Installation of Tool X, Site Y</i>	<i>Project Manager</i>	<i>1</i>	<i>7</i>	<i>100</i>	<i>700</i>
	<i>Installation specialist</i>	<i>2</i>	<i>10</i>	<i>100</i>	<i>1000</i>
	<i>Engineer</i>	<i>1</i>	<i>9</i>	<i>100</i>	<i>900</i>
<i>Installation of Tool X, Site Z</i>	<i>Project Manager</i>	<i>1</i>	<i>5</i>	<i>100</i>	<i>700</i>
	<i>Installation specialist</i>	<i>1</i>	<i>5</i>	<i>100</i>	<i>1000</i>
	<i>Engineer</i>	<i>1</i>	<i>9</i>	<i>100</i>	<i>900</i>
<i>Training Site X</i>	<i>Project Manager</i>	<i>1</i>	<i>.</i>	<i>100</i>	<i>...</i>
<i>...</i>	<i>...</i>	<i>.</i>	<i>.</i>	<i>...</i>	<i>...</i>
<i>...</i>	<i>...</i>	<i>.</i>	<i>.</i>	<i>...</i>	<i>...</i>
GRAND TOTALS					

Notes:

- Licence fees:** Where a pre-developed software package with license costs is being proposed, a proposal for the appropriate licence(s) should be included as a formal deliverable. The resource profiles, total number of days, and daily rate columns should be left blank. Pricing should be included in the total column.
- Support:** Support should be costed as a separate formal deliverable on the basis of the Contract duration, either as a total cost or as a cost per installation site (as appropriate).
- Additional or Integrated Costs:** Where there are additional costs (e.g. software configuration) that could be modularised, these should be outlined, and similarly, where any element is not separately priced it should be indicated that the overall figure provided includes this deliverable where applicable.

Date:

Signature of authorised representative:

(Print name):

Position in Company:

ANNEX II - EXCLUSION CRITERIA STATEMENT AND DETAIL OF SUPPORTING DOCUMENTATION REQUIRED

Tenderers must:

- Answer the following questions by indicating yes or no in each case. Any tenderer answering yes to any of these questions shall be excluded from participation in this tender.
- Provide the supporting documents listed below in support of these answers.
- Provide the signed declaration regarding conflict of interest detailed on the next page.

- | | | |
|----|--|--------|
| 1 | Is the Tenderer insolvent (or the subject of bankruptcy proceedings if an individual) or being wound up? | Yes/no |
| 2 | Is the Tenderer having its affairs administered by the courts? | Yes/no |
| 3 | Has the Tenderer entered into an arrangement with creditors? | Yes/no |
| 4 | Has the Tenderer suspended business activities? | Yes/no |
| 5 | Is the Tenderer the subject of proceedings concerning any such matters referred to in 1, 2, 3 or 4 above or in any analogous situation arising from a similar procedure provided for in national legislation or regulations? | Yes/no |
| 6 | Has the Tenderer been convicted of any offence (if an individual) or judgment been made against it concerning its professional conduct by a judgment which has the force of res judicata? | Yes/no |
| 7 | Has the Tenderer been guilty of grave professional misconduct? | Yes/no |
| 8 | Has the Tenderer failed to fulfil its obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed? | Yes/no |
| 9 | Has the Tenderer been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the European Community's financial interests? | Yes/no |
| 10 | Following any other procurement procedure or grant award procedure financed by the European Community budget, has the Tenderer been declared to be in serious breach of contract for failure to comply with their contractual obligation? | Yes/no |

Supporting documentation to be provided:

In support of the above responses, please provide the following documents:

Proof regarding situations mentioned in points 1, 2, 3, 4, 5, 6 and 9 in the form of a recent extract from the judicial record, or failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that these requirements are satisfied. The extract(s) or equivalent documentation must be the most reasonably available.

The EMEA will accept a recent certificate issued by the competent authority of the country concerned as satisfactory evidence that the Tenderer is not in the situation mentioned in point 8 above. The certificate must be dated less than four months before the final date for submission of tenders.

Where no such certificate is issued in the country concerned, it may be replaced by a sworn or a solemn statement made by the Tenderer before a judicial or administrative authority, a notary or a qualified professional body in the country of origin or provenance.

Tenderers should also provide a declaration to confirm that there is no conflict of interest as follows:

- that they do not have any conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinities, family or emotional ties, or any other relevant connection or shared interest;
- that they will inform EMEA, without delay, of any situation constituting a conflict of interest or which could give rise to a conflict of interest;
- that they have not made and will not make any offer of any type whatsoever from which an advantage can be derived under the contract;
- that they have not granted and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to the award of the contract.

EMEA reserves the right to check the responses to the above information.

**ANNEX III – SUMMARY CHECKLIST OF DOCUMENTS WHICH TENDERERS MUST
SUBMIT**

1. Letter enclosing the tender on the official letter headed paper of the company and signed by an authorised representative of that company.
2. Tender in two copies (one original, clearly marked as original, and one copy), containing the following elements:
 - A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
 - Information sheet on the tenderer.
 - Completed questionnaire in Annex II relating to Exclusion Criteria AND supporting documentation together with declaration regarding conflict of interests.
 - Documentation requested to enable assessment of Selection Criteria .
 - Documentation requested to enable assessment of Award Criteria .
 - A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with EMEA.
 - An undertaking to inform EMEA promptly following any matter which would alter or add to any of the information given in response to this tender.
 - Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
 - **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex I, and exclusive of VAT, signed by an authorised representative of the tenderer.

* * * * *

ANNEX IV - DRAFT FRAMEWORK CONTRACT: SUPPLY AND SERVICE

CONTRACT NUMBER EMEA/2006/34/PM

European Medicines Agency (hereinafter referred to as "EMA"), which is represented for the purposes of the signature of this contract by Mr Hans-Georg Wagner, Head of Unit for Communications and Networking

of the one part,

and

[official name in full of company and statutory registration number of company]
whose registered address is at [official address in full]

(hereinafter referred to as "the Contractor"), represented for the purposes of the signature of this contract by [name in full and title], a duly authorised officer of the Contractor,

of the other part,

HAVE AGREED

the **Special Conditions** and the **General Conditions** below and the following Annexes:

Annex I – Tender Specifications (Invitation to Tender No EMEA/2006/34/PM of [complete])

Annex II – Contractor's Tender (No [complete] of [complete])

Annex III – Sample Specific Contract

Annex IV – Conditions for Informatics Contracts

Annex V – Service Level Agreement

[Other Annexes]

which form an integral part of this framework contract (hereinafter referred to as "the Contract").

In the event of any conflict herein, the terms set out in the Special Conditions shall take precedence over those in the other parts of the Contract. The terms set out in the General Conditions shall take precedence over those in the Annexes except for Annex IV, which shall take precedence over the General Conditions. The terms set out in the Specific Contracts (as defined below) shall take precedence over those in the Contract. The terms set out in the Tender Specifications (Annex I) shall take precedence over those in the Tender (Annex II).

For the avoidance of doubt, the Contractor acknowledges and agrees that the terms of the Contract shall apply to the exclusion of the Contractor's standard terms and conditions.

Subject to the above, the several instruments forming part of the Contract are to be taken as mutually explanatory. Ambiguities or discrepancies within or between such parts shall be explained or rectified by a written instruction issued by EMA, subject to the rights of the Contractor under Article I.7 should it dispute any such instruction.

I – SPECIAL CONDITIONS

ARTICLE I.1 - SUBJECT

- I.1.1.** The subject of the Contract is the provision of software including acquisition of software licences, installation, configuration, training and training material, support and maintenance. The goods and services covered by this Contract are set out in Annex I (the "Goods" and the "Services").
- I.1.2.** Execution of the Contract imposes no obligation on EMEA to purchase the Goods or the Services. Only the implementation of the Contract through specific contracts in the form set out at Annex III ("Specific Contract") are binding on EMEA and authorises implementation of the supply of the Goods and the provision of the Services ("Implementation").
- I.1.3.** Upon Implementation, the Contractor shall supply the Goods and provide the Services in accordance with Annex I.
- I.1.4.** The Contract does not confer on the Contractor any exclusive right to supply the Goods or provide the Services described in Annex I to EMEA.
- I.1.5.** The Goods and Services shall be provided either at EMEA's office premises in London or, at EMEA's direction, the office premises of the National Competent Authorities of European Union Member States, as may be specified in the relevant Specific Contract.

ARTICLE I.2 – DURATION AND IMPLEMENTATION OF THE CONTRACT

- I.2.1.** The Contract and Specific Contracts shall become effective on the date on which they are signed by the last contracting party.
- I.2.2.** Under no circumstances may Implementation take place before the date on which the Contract and Specific Contracts issued hereunder have become effective.
- I.2.3.** This Contract is concluded for a period of 48 months from the date on which it becomes effective. This contractual period and all other periods specified in the Contract are calculated in calendar months unless otherwise indicated. The Contract may be renewed up to twice thereafter for support and maintenance Services only, each time for a period of execution of Services of 12 months, with the express written agreement of the parties before the expiry of the Contract. Renewal does not imply any modification or deferment of existing obligations.
- I.2.4.** The Specific Contracts must become effective before this Contract expires by effluxion of time or is terminated. The Contract shall continue to apply to such Specific Contracts after its expiry or termination, but no later than six months.
- I.2.5.** The Goods shall be delivered to, and the Services performed at, the EMEA at 7 Westferry Circus, Canary Wharf, London E14 4HB or, pursuant to Article I.1.5 above, to the office premises of such National Competent Authority of such European Union Member State(s) (the "Applicable NCA") as shall be directed by EMEA in accordance with the instructions of duly authorised staff of said Applicable NCA. Deliveries may be made on any working day during normal working hours, at the agreed place of delivery.
- I.2.6.** Within five working days of a request for Goods and Services being sent by EMEA, the Contractor shall return a duly justified estimate of the resources to be allocated for the execution thereof. Within five working days of a Specific Contract being sent by EMEA, the Contractor shall return it, duly signed and dated.

ARTICLE I.3 – CONTRACT PRICE

- I.3.1.** The amount payable for the Goods and the Services shall be as listed in Annex II exclusive of VAT covering all the Goods supplied and the Services provided (the “Charges”).
- I.3.2.** It is agreed that the Charges include all other expenditure that may be incurred by the Contractor in performance of this Contract, including travel, subsistence or any other related expenses.
- I.3.3.** The Charges shall be fixed and not subject to revision for Specific Contracts concluded during the first year of performance of the Contract.

From the beginning of the second year of performance of the Contract, the Charges may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the Contract became effective in accordance with Article I.2.1 above. Specific Contracts shall be concluded on the basis of the Charges in force on the date on which they become effective. Such Charges shall not be subject to revision.

A revision shall be determined by the trend in European Index of Consumer Prices (EICP) published by the Statistical Office of the European Communities in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (<http://europa.eu.int/comm/eurostat/>).

Accordingly a revision shall be calculated in accordance with the following formula:

$$Ar = Ao \frac{Ir}{Io}$$

where

- Ar = revised total amount;
Ao = total amount in the original tender;
Io = index for the month in which the validity of the tender expires;
Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices.

ARTICLE I.4 – PAYMENT PERIODS AND FORMALITIES

- I.4.1.** Payment of the Charges under the Contract shall be made only if the Contractor has fulfilled all its contractual obligations by the date on which the invoice is correctly submitted. Payment requests may not be made if payments for previous periods have not been executed as a result of default or negligence on the part of the Contractor.
- 1.4.2.** Payments shall be made on the basis of an invoice issued by the Contractor and verified by EMEA. Any invoice must give a breakdown of the Charges and a statement of reimbursable expenses in accordance with Article I.3.2. Subject to verification by EMEA, payment shall be made within 45 days of receipt of the invoice.
- 1.4.3.** The payment periods for the Charges will be stipulated in the relevant Specific Contracts.
- 1.4.4.** No financial guarantee or performance guarantee will be required.

ARTICLE I.5 – BANK ACCOUNT

Payments shall be made direct to the Contractor’s bank account, identified as follows:

Name of bank: [complete]
Address of branch in full: [complete]
Exact designation of account holder: [complete]
Full account number including codes: [complete]
IBAN code: [complete]

ARTICLE I.6 – NOTICE / ADMINISTRATIVE PROVISIONS

Any notice or other communication relating to the Contract shall be made in writing and shall bear the Contract number. Ordinary mail shall be deemed to have been received by EMEA on the date on which it is registered by the department responsible indicated below. All notices or other communications shall be sent to the following addresses:

EMEA:

EMEA
Project Management Sector
7 Westferry Circus
Canary Wharf
London E14 4HB
UK

Contractor:

Mr/Mrs/Ms [complete]
[Title]
[Company name]
[Official address in full]

ARTICLE I.7– APPLICABLE LAW AND SETTLEMENT OF DISPUTES

- I.7.1.** The Contract shall be governed and construed in accordance with the laws of England & Wales.
- I.7.2.** Failing an amicable settlement, the Court of Justice of the European Communities shall have exclusive jurisdiction in any dispute relating to the performance or the interpretation of the Contract.

ARTICLE I.8 – TERMINATION BY EITHER CONTRACTING PARTY

EMEA may, but the Contractor may not, of its own volition and without being required to pay compensation, terminate the Contract by serving three months' formal prior notice. In the case of Goods, should EMEA terminate the Contract, the Contractor shall only be entitled to payment corresponding to the Goods which are the subject of valid Specific Contracts before the date termination is notified to become effective ("Termination Date"). In the case of Services, should EMEA terminate the Contract, the Contractor shall only be entitled to payment corresponding to the Services which are the subject of valid Specific Contracts before the date termination is notified to become effective. On receipt of such notice from EMEA the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce its commitments in relation to EMEA. It shall draw up any documents required by the Contract and its Annexes for the Goods delivered and Services provided up to the Termination Date, within a period not exceeding sixty days from the Termination Date.

ARTICLE I.9 – SERVICE LEVEL AGREEMENT

EMEA and the Contractor shall negotiate and sign a Service Level Agreement (“SLA”) within six months following entry into force of the Contract. The SLA shall be incorporated into the Contract by way of an amendment and shall be deemed to form Annex V of it.

The scope of the SLA shall be to clearly define the Contract management procedures and to fix appropriate quality indicators and the levels for the provision of Services and for the Contract administration.

II – GENERAL CONDITIONS

ARTICLE II.1 – PERFORMANCE OF THE CONTRACT

II.1.1. The Contractor shall supply the Goods of the highest possible quality and perform the Services to the highest professional standards. The Contractor shall have sole responsibility for complying with any legal obligations incumbent on it, notably but not limited to those resulting from employment, tax and social legislation.

II.1.2. The Contractor shall have sole responsibility for taking the necessary steps to obtain any permit or licence required for the supply of the Goods and the performance of the Services under the laws and regulations in force at the place where the Services are to be provided.

II.1.3. Without prejudice to Article II.3 any reference made to any employee, director or other officer or member of staff of the Contractor (“Contractor’s Staff”) in the Contract shall relate exclusively to individuals involved in the performance of the Services.

II.1.4. The Contractor must ensure that any of the Contractor’s Staff performing the Contract have the professional qualifications and experience required for the performance of the Services assigned to them.

II.1.5. The Contractor shall neither hold itself out as representing EMEA nor behave in any way that would give such an impression. The Contractor shall inform third parties that it does not belong to the European public service.

II.1.6. The Contractor shall have sole responsibility for the Contractor’s Staff who perform the Services assigned to them.

The Contractor shall make provision for the following employment or service relationships with the Contractor’s Staff:

- the Contractor’s Staff performing the Services assigned to the Contractor may not accept orders or instructions direct from EMEA;
- EMEA may not under any circumstances be considered to be the employer of the Contractor’s Staff and the said staff shall undertake if requested by EMEA and as far as they are able not to invoke in respect of EMEA any right arising from the contractual relationship between EMEA and the Contractor.

II.1.7. Notwithstanding the above, the Contractor shall indemnify and hold EMEA harmless against all and any claims, loss, cost or expenses suffered as a consequence of any claim arising from any employee or other member of the Contractor’s Staff or any claim, assessment or other levy made by any competent taxation or other governmental agency in connection with the provision of the Services by the Contractor to EMEA.

- II.1.8.** In the event of disruption resulting from the action of a member of the Contractor's Staff working on EMEA's premises or in the event of the expertise of a member of the Contractor's Staff failing to correspond to the profile required by the Contract, the Contractor shall replace him without delay. EMEA shall have the right to request the replacement of any such member of the Contractor's Staff, stating its reasons for so doing. Replacement staff must have the necessary qualifications and be capable of performing the Contract under the same contractual conditions. The Contractor shall be responsible for any delay in the execution of the Services assigned to it resulting from the replacement of the Contractor's Staff in accordance with this Article.
- II.1.9.** Should any unforeseen event, action or omission directly or indirectly hamper execution of the Services, either partially or totally, the Contractor shall immediately and on its own initiative record it and report it to EMEA. The report shall include a description of the problem and an indication of the date on which it started and of the remedial action taken by the Contractor to ensure full compliance with its obligations under the Contract. In such event the Contractor shall give priority to solving the problem rather than determining liability.
- II.1.10.** Should the Contractor fail to perform its obligations under the Contract in accordance with the provisions laid down therein, EMEA may - without prejudice to its right to terminate the Contract - reduce or recover payments in proportion to the scale of the failure. In addition, EMEA may impose penalties or liquidated damages provided for in Article II.17.

II.1.11 Phases of execution of purchase of Goods

Whenever EMEA requests Goods to be supplied pursuant to the Contract, it shall send a Specific Contract to the Contractor, specifying the terms of supply of the Goods, such as quantity, designation, quality, price, place of delivery and time allowed for delivery, in accordance with the conditions laid down in the Contract.

Acknowledgment of the Specific Contract by the Contractor

Within the period indicated in Article I.2.6, the Contractor shall return one original of the Specific Contract, duly signed and dated, thereby acknowledging receipt of the Specific Contract and acceptance of the terms.

Delivery

a) Time allowed for delivery

The time allowed for delivery shall be stipulated in the Specific Contract and calculated in accordance with Article I.2.

b) Date, time and place of delivery

EMEA shall be notified in writing of the exact date of delivery within the period indicated in Article I.2. All deliveries shall be made at the agreed place of delivery during the hours indicated in Article I.2.

The Contractor shall bear all costs and risks involved in delivering the Goods to the place of delivery.

c) Consignment note

Each delivery shall be accompanied by a consignment note in duplicate, duly signed and dated by the Contractor or its carrier, giving the Specific Contract reference number and particulars of the Goods delivered. One copy of the consignment note shall be countersigned by EMEA and returned to the Contractor or to its carrier.

Certificate of conformity

Signing of the consignment note by EMEA, as provided for in subparagraph c) above, is simply an acknowledgment of the fact that the goods have been delivered and in no way implies conformity of the Goods with the Specific Contract.

Conformity of the Goods delivered shall be evidenced by the signing of a certificate to this effect by EMEA no later than one month after the date of delivery, unless provision is made for a different period in the Special Conditions or in Annex I.

Conformity shall be declared only where the conditions laid down in the Contract and in the Specific Contract are satisfied and the Goods conform to Annex I.

Where, for reasons attributable to the Contractor, EMEA is unable to accept the Goods, the Contractor shall be notified in writing at the latest by the deadline for conformity.

Conformity of the Goods delivered with the Contract

- a) The Goods delivered by the Contractor to EMEA must be in conformity in quantity, quality, price and packaging with the Contract and the relevant Specific Contract.
- b) The Goods delivered must:
 - correspond to the description given in Annex I and possess the characteristics of the Goods supplied by the Contractor to EMEA as a sample or model;
 - be fit for any specific purpose required of them by EMEA and made known to the Contractor at the delivery of the Specific Contract;
 - be fit for the purposes for which goods of the same type as the Goods are normally used;
 - demonstrate the quality and performance which are normal in goods of the same type as the Goods and which EMEA can reasonably expect, given the nature of the Goods and taking into account any public statements on the specific characteristics of the Goods made by the Contractor, the producer or the manufacturer or its representative, particularly in advertising or on labelling;
 - be packaged according to the usual method for goods of the same type as the Goods or, failing this, in a way designed to preserve and protect them.

Remedy

- a) The Contractor shall be liable to EMEA for any lack of conformity which exists at the time the Goods are verified.
- b) In case of lack of conformity, without prejudice to Article II.17 regarding liquidated damages applicable to the total Charge for the Goods concerned, EMEA shall be entitled:
 - either to have the Goods brought into conformity, free of charge, by repair or replacement;
 - or to have an appropriate reduction made in the Charges.
- c) Any repair or replacement shall be completed within a reasonable time and without any significant inconvenience to EMEA, taking account of the nature of the Goods and the purpose for which they are required by EMEA.
- d) The term 'free of charge' in paragraph b) refers to the costs incurred to bring the Goods into conformity, particularly the cost of postage, labour and materials.

Assembly

If required by Article I.1.3 of the Special Conditions, the Contractor shall assemble the Goods delivered within a period of one month unless otherwise specified in the Special Conditions or in Annex 1.

Notwithstanding any liability conferred on the Contractor by any other relationship between the parties, any lack of conformity resulting from incorrect installation of the Goods delivered shall be deemed to be equivalent to lack of conformity of the Goods if installation forms part of the Contract and the Goods were installed by the Contractor or under its responsibility. This shall apply equally if the Goods were to be installed by EMEA and were incorrectly installed owing to a shortcoming in the installation instructions.

Services provided to goods

If required by Annex I, Services to goods shall be provided accordingly.

II.1.12 General provisions concerning goods

a) Packaging

The Goods shall be packaged in strong boxes or crates or in any other way that ensures that the contents remain intact and prevents damage or deterioration. Packaging, pallets and their contents (including the Goods), shall not weigh more than 2000 kg which represents the limit of the pallet transporter of EMEA.

Unless otherwise specified in the Special Conditions or in Annex I, pallets shall be considered as one-way packaging and may be disposed of by EMEA and will not be returned to the Contractor regardless of whether the Goods have been rejected. Each box shall be clearly labelled with the following information:

- EMEA and address for delivery;
- name of Contractor;
- description of contents;
- date of delivery;
- reference number and date of the Specific Contract;
- EC code number of article.

b) Guarantee

The Goods shall be guaranteed against all defects in manufacture or materials for two years from the date of delivery, unless provision is made for a different period in Annex I.

The Contractor shall ensure and represents and warrants that any permits and licences required for manufacturing and selling the Goods have been obtained.

The Contractor shall replace at its own expense, within a reasonable time limit to be determined by agreement between the parties, any items which become damaged or defective in the course of normal use during the guarantee period.

The Contractor is responsible for any conformity defect which exists at the time of delivery, even if this defect does not become apparent until a later date.

The Contractor is also responsible for any conformity defect which occurs after delivery and is ascribable to non-compliance with its obligations, including failure to provide a guarantee that, for a certain period, goods used for the purposes for which they are normally used or for a specific purpose will preserve their qualities or characteristics as specified.

If part of an item is replaced, the replacement part shall be guaranteed under the same terms and conditions for a further period of the same duration as that specified above.

If a defect is found to originate in a systematic flaw in design, the Contractor must replace or modify all identical parts incorporated in the other Goods that are part of the Specific

Contract, even though they may not have been the cause of any incident. In this case, the guarantee period shall be extended as stated above.

ARTICLE II.2 – LIABILITY

- II.2.1.** EMEA shall not be liable for any claim, loss, cost or expense sustained by the Contractor in performance of the Contract except in the event of wilful misconduct or gross negligence on the part of EMEA.
- II.2.2.** The Contractor shall be liable for any claim, loss, cost or expenses sustained by EMEA or any Applicable NCA but caused by the performance of the Contract, including that arising in the event of subcontracting under Article II.13. EMEA shall not be liable for any act or default on the part of the Contractor in performance of the Contract.
- II.2.3.** The Contractor shall indemnify and hold EMEA and/or any Applicable NCA harmless and provide compensation in the event of any action, claim or proceeding brought against EMEA by a third party caused by the Contractor in performance of the Contract.
- II.2.4.** In the event of any action brought by a third party against EMEA and/or any Applicable NCA in connection with performance of the Contract, the Contractor shall assist EMEA and/or any Applicable NCA. Expenditure incurred by the Contractor to this end may be borne by EMEA.
- II.2.5.** The Contractor shall take out and maintain for the duration of the Contract insurance against all normal business risks and damage relating to performance of the Contract including but not limited to Employer's Liability Insurance (if applicable) and Public Liability Insurance, both to a minimum cover of £5,000,000.00 or the equivalent in Euro. If required by the relevant applicable legislation, the Contractor shall take out supplementary insurance as reasonably required in accordance with reasonably prudent practices in its industry. A copy of all the relevant insurance contracts shall be sent to EMEA should it so request.

ARTICLE II.3 - CONFLICTS OF INTEREST

- II.3.1.** The Contractor shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the Contract. Such conflicts of interest could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. Any conflicts of interest which could arise during performance of the Contract must be notified to EMEA in writing without delay. In the event of any such conflict, the Contractor shall immediately take all necessary steps to resolve it.

EMEA reserves the right to verify that such measures are adequate and may require additional measures to be taken, if necessary, within a time limit which it shall set. The Contractor shall ensure that the Contractor's Staff are not placed in a situation which could give rise to conflicts of interest. Without prejudice to Article II.1 the Contractor shall replace, immediately and without compensation from EMEA, any member of the Contractor's Staff exposed to such a situation.

- II.3.2.** The Contractor shall abstain from entering into any contract likely to compromise its independence.
- II.3.3.** The Contractor declares:
- that it has not made and will not make any offer or agreement with any third party of any type whatsoever from which an advantage can be derived under the Contract,
 - that it has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any third party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or

indirectly, inasmuch as it is an incentive or reward relating to performance of the Contract.

- II.3.4.** The Contractor shall pass on all the relevant obligations in writing to the Contractor's Staff as well as to third parties involved in performance of the Contract. A copy of the instructions given and the undertakings made in this respect shall be sent to EMEA should it so request.

ARTICLE II.4 – PAYMENTS

II.4.1. Not applicable.

II.4.2. Not applicable.

II.4.3. Not applicable.

II.4.4. If any reports to be submitted by the Contractor are a condition for payment, on receipt EMEA shall have the following time for approval of such reports:

- a) 20 calendar days for straightforward contracts relating to services;
- b) 60 calendar days for contracts involving technical services, which are particularly complex to evaluate.

EMEA may either approve the report, with or without comments or reservations, or suspend such time period and request additional information, or reject the report and request a new report. If EMEA does not react within the above time limits, the report shall be deemed to have been approved. Approval of the report does not imply recognition either of its regularity or of the authenticity, completeness or correctness of the declarations or information enclosed. Any new report requested shall be subject to the above provisions.

ARTICLE II.5 – GENERAL PROVISIONS CONCERNING PAYMENTS

II.5.1. Payments shall be deemed to have been made on the date on which EMEA's account is debited.

II.5.2. The payment period referred to in Article I.4 may be suspended by EMEA at any time if it informs the Contractor that its invoice is incorrect, either because the amount is not due or because the necessary supporting documents have not been properly produced. In case of doubt on the eligibility of the expenditure indicated in the payment request, EMEA may suspend the time limit for payment for the purpose of further verification, including an on-the-spot check, in order to ascertain, prior to payment, that the expenditure is eligible.

EMEA shall notify the Contractor accordingly by registered letter with acknowledgement of receipt or equivalent. Suspension shall take effect from the date of dispatch of the letter. The remainder of the period referred to in Article I.4 shall begin to run again once the suspension has been lifted.

II.5.3. In the event of late payment caused other than by the Contractor's default the Contractor may claim interest within two months of receiving the payment. Interest shall be calculated at the rate applied by the European Central Bank to its most recent main refinancing operations ("*the reference rate*") plus seven percentage points ("*the margin*"). The reference rate in force on the first day of the month in which the payment is due shall apply. Such interest rate is published in the C series of the Official Journal of the European Union. Interest shall be payable for the period elapsing from the calendar day following expiry of the time limit for payment up to the day of payment. Suspension of payment by EMEA may not be deemed to constitute late payment.

ARTICLE II.6 – RECOVERY

- II.6.1.** If total payments made exceed the amount actually due under the Contract or if recovery is justified in accordance with the terms of the Contract, the Contractor shall reimburse the appropriate amount on receipt of the debit note, in the manner and within the time limits set by EMEA.
- II.6.2.** In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article II.5.3. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.
- II.6.3.** EMEA may, after informing the Contractor, recover amounts established as certain, of a fixed amount and due by offsetting, in cases where the Contractor also has a claim on the Communities that is certain, of a fixed amount and due. EMEA may also claim against any guarantee, where provided for.

ARTICLE II.7 – NOT APPLICABLE

ARTICLE II.8 – OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

- II.8.1.** Any copyright, trademarks, tradenames, designs or patents (whether registered or unregistered) including all other intellectual or industrial property rights (the “Intellectual Property Rights”), arising, or created by the Contractor, in the performance of the Contract, shall be owned solely by EMEA, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation.
- II.8.2.** Other than as may be agreed to the contrary, where Intellectual Property Rights exist prior to the Contract being entered into and are utilised in the Goods or the provision of the Services, and ongoing benefit of those Goods and Services, the Contractor shall, or shall procure that any third party owner of said Intellectual Property Rights shall, grant to EMEA a perpetual, royalty free licence in connection therewith.
- II.8.3.** The Contractor shall execute any documents and do all things necessary to vest the Intellectual Property Rights, referred to in Article II.8.1 above, in the ownership of EMEA as may be requested by EMEA from time to time.
- II.8.4.** The Contractor represents and warrants that the Intellectual Property Rights arising, or utilised, in accordance with Articles II.8.1-2 are or shall be original and will not infringe any Intellectual Property Rights owned by any third party (including, but without limitation to, all moral rights).

ARTICLE II.9 – CONFIDENTIALITY

- II.9.1.** In this Article, “Information” shall include any information intentionally or unintentionally provided directly or indirectly by either EMEA or the Contractor to the other in oral or documentary form or by way of electronically accessible media or other tangible form or by demonstrations and whether created or arising in connection with the Goods and/or Services or existing before, on or after the date of the Contract.
- II.9.2.** In this Article, “Confidential Information” shall mean:
- (a) in respect of Information provided in documentary or by way of a presentation or in other tangible form, Information which at the time of provision is marked or otherwise designated to show expressly or is created or arises as a consequence of the provision of the Goods and/or Services or by necessary implication that it is imparted in confidence; and

- (b) in respect of Information that is imparted orally, any information that EMEA or its representatives informed at the time of disclosure was imparted in confidence; and
- (c) in respect of Confidential Information imparted orally, any note or record of the disclosure; and
- (d) any copy of any of the foregoing; and
- (e) the fact that Goods and/or Services are being provided hereunder.

II.9.3. The Contractor undertakes to treat in the strictest confidence and not make use of or divulge or disclose to any third parties any Confidential Information. The Contractor shall continue to be bound by this undertaking after the termination or expiry of this Contract.

II.9.4. The Contractor shall obtain from each member of the Contractor's Staff an undertaking that they will respect the confidentiality of any of the Confidential Information and that they will not divulge or disclose to any third parties or use for their own benefit or that of any third party any Confidential Information not available publicly, even after termination or expiry of this Contract.

ARTICLE II.10 - USE, DISTRIBUTION AND PUBLICATION OF INFORMATION

II.10.1. The Contractor shall authorise EMEA to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, any data contained in or relating to the Contract, in particular the identity of the Contractor, the subject matter, the duration, the amount paid and any Confidential Information (as defined in Article II.9 above).

II.10.2. Unless otherwise provided by the Special Conditions, EMEA shall not be required to distribute or publish the Confidential Information supplied in performance of the Contract. If it decides not to publish the documents or information supplied, the Contractor may not have them distributed or published elsewhere without prior written authorisation from EMEA.

II.10.3. Any distribution or publication of information relating to the Contract by the Contractor shall require prior written authorisation from EMEA and shall mention the amount paid by EMEA. It shall state that the opinions expressed are those of the Contractor only and do not represent EMEA's official position.

II.10.4. The use of Confidential Information obtained by the Contractor in the course of the Contract for purposes other than its performance shall be forbidden, unless EMEA has specifically given prior written authorisation to the contrary.

ARTICLE II. 11 – TAXATION

II.11.1. The Contractor shall have sole responsibility for compliance with the tax laws which apply to it. Failure to comply shall render the relevant invoices invalid.

II.11.2. The Contractor recognises that EMEA is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities.

II.11.3. The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the Goods and Services required for performance of the Contract are exempt from taxes and duties, including VAT (if applicable).

- II.11.4.** Invoices presented by the Contractor shall indicate its place of taxation for VAT purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

ARTICLE II.12 – FORCE MAJEURE

- II.12.1.** Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties including acts of terrorism which prevents either of them from performing any of their obligations under the Contract, was not due to error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence. Defects in equipment or material or delays in making it available, labour disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.
- II.12.2.** Without prejudice to the provisions of Article II.1.9, if either party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgement of receipt or equivalent, stating the nature, likely duration and foreseeable effects.
- II.12.3.** Neither party shall be held in breach of its contractual obligations if it has been prevented from performing them by force majeure. Where the Contractor is unable to perform its contractual obligations owing to force majeure, it shall have the right to remuneration only for the Goods actually delivered and Services actually executed.
- II.12.4.** The contracting parties shall take all necessary measures to reduce damage to a minimum including the right of EMEA to terminate and retain new suppliers.

ARTICLE II.13 – SUBCONTRACTING

- II.13.1.** The Contractor shall not subcontract the supply of the Goods and the performance of the Services without prior written consent from EMEA nor cause the Contract to be performed in fact by third parties.
- II.13.2.** Even where EMEA authorises the Contractor to subcontract to third parties, the Contractor shall remain bound by its obligations to EMEA under the Contract and shall guarantee the supply of the Goods and the provision of the Services and be liable for the proper performance of the Contract as if it were supplying the Goods and performing the Services itself.
- II.13.3.** The Contractor shall ensure that the subcontracting of its obligations does not affect rights and guarantees to which EMEA is entitled by virtue of the Contract and agrees to indemnify EMEA against any claim, loss, cost and expenses sustained by EMEA as a consequence thereof.

ARTICLE II.14 – ASSIGNMENT

- II.14.1.** The Contractor shall not assign the rights and obligations arising from the Contract, in whole or in part, without prior written consent from EMEA. However on one month's prior written notice, EMEA may assign any right or obligation or novate the whole Contract to any Applicable NCA it deems necessary and the Contractor expressly agrees thereto and undertakes to execute any and all documentation reasonably required therefor.
- II.14.2.** In the absence of the authorisation referred to in II.14.1 above, or in the event of failure to observe the terms thereof, assignment by the Contractor shall be void against and shall have no effect on EMEA.

ARTICLE II.15 – TERMINATION BY EMEA

II.15.1. Notwithstanding any other term of this Contract, EMEA may terminate the Contract forthwith in the following circumstances:

- (a) where the Contractor is unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986, is being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations applicable to the Contractor;
- (b) where the Contractor is an individual, he has been convicted of a criminal offence by a judgement which has the force of *res judicata* (other than minor road traffic offences which do not affect the provision of the Services);
- (c) where the Contractor has been sanctioned for professional misconduct proven by any means which the sanctioning authority can reasonably justify;
- (d) where EMEA has reasonable grounds to suspect the Contractor of fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to EMEA's financial and/or reputational interests;
- (e) where the Contractor was guilty of misrepresentation in supplying the information in the Contractor's Tender or required by EMEA as a condition of entering into the Contract or failed to supply this information;
- (f) where there is a change of control of the Contractor and or any holding company of the Contractor whereby EMEA (acting reasonably at all times) considers there is a material detriment to its financial situation or its ability to carry out its functions in the way expected of it. In this clause (f), control means the ability to direct the affairs of another, whether by way of contract, ownership of shares or otherwise howsoever;
- (g) where the Contractor has not fulfilled obligations relating to the payment of social security contributions or the payment of taxes, whether or not in connection with the Contractor's Staff, in accordance with the legal provisions of the country in which it is established or with those of the country applicable to the Contract or those of the country where the Contract is to be performed;
- (h) where the Contractor is in breach of any obligations under Articles II.3 and II.9.

II.15.2. Notwithstanding any other term of this Contract, EMEA may terminate the contract forthwith in the following circumstances:

- (a) where a change in the Contractor's legal, financial, technical or organisational situation could, in EMEA's reasonable opinion, have a significant effect on the performance of the Contract;
- (b) where delivery of the Goods has not actually commenced within fifteen days of the date agreed and/or where provision of the Services has not actually commenced within three months of the date agreed, and the new date(s) proposed, if any, is considered unacceptable by EMEA;
- (c) where the Contractor is unable, through its own fault, to obtain any permit or licence required for performance of the Contract;
- (d) where the Contractor is in breach of any other obligations hereunder;

PROVIDED the Contractor fails to remedy said breach, only after receiving formal notice in writing to remedy said breach which specifies the nature of the alleged breach and gives the Contractor the opportunity to remedy the breach within a reasonable period following receipt of the formal notice but in any event not exceeding 14 days.

II.15.3. In case of force majeure, notified in accordance with Article II.12, either contracting party may terminate the Contract at any time, where performance thereof cannot be ensured for a period corresponding to at least one fifth of the period laid down in Article I.2.3 immediately following the event amounting to force majeure occurring.

II.15.4. Prior to termination under point a), b), c), or d) of Article II.15.2, the Contractor shall be given the opportunity to submit its observations.

II.15.5. Termination shall take effect on the date on which a notice with pro-forma acknowledgement of receipt attached terminating the Contract is received by the Contractor, or on any other date indicated in the notice.

II.15.6. Consequences of termination:

In the event of EMEA terminating the Contract in accordance with this Article and without prejudice to any other measures provided for in the Contract, the Contractor shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the letter terminating the Contract, the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce its commitments. The Contractor shall draw up any documents required by the Special Conditions for the Goods already supplied or the Services already performed up to the date on which termination takes effect, within a period not exceeding sixty days from that date.

EMEA may claim compensation for any damage suffered and recover any sums paid to the Contractor under the Contract.

On termination EMEA may engage any other contractor to supply the Goods and provide the Services. EMEA shall be entitled to claim from the Contractor all extra costs incurred in making good and completing the supply of Goods and provision of Services, without prejudice to any other rights or guarantees it has under the Contract.

ARTICLE II.16 - CANCELLATION OF SPECIFIC CONTRACTS

Where execution of a Specific Contract has not actually commenced within three months of the date foreseen for the commencement of execution and the new date proposed, if any, is considered unacceptable by EMEA, EMEA may cancel such Specific Contract with no prior notice. Cancellation shall take effect from the day after the day on which the Contractor receives a registered letter with acknowledgement of receipt or equivalent.

EMEA may cancel a Specific Contract at any time during execution thereof on the grounds and under the conditions set out in Article II.15 with respect to the part still outstanding. The Contractor shall accept, as the aggregate liability of EMEA, payment of the price of the Goods delivered or Services provided by it as at the effective date of cancellation.

ARTICLE II.17 – LIQUIDATED DAMAGES

Should the Contractor fail to perform its obligations under the Contract within the time limits set by the Contract, then, without prejudice to the Contractor's actual or potential liability incurred in relation to the Contract or to EMEA's right to terminate the Contract, EMEA may decide to impose liquidated damages of 0.2% of the amount specified in the relevant Specific Contract per calendar day of delay. The Contractor may submit arguments against this decision within thirty days of notification by registered letter with acknowledgement of receipt or equivalent. In the absence of reaction on its part or of written withdrawal by EMEA within thirty days of the receipt of such arguments, the decision

imposing the liquidated damages shall become enforceable. These liquidated damages shall not be imposed where there is provision for interest for late completion. EMEA and the Contractor expressly acknowledge and agree that any sums payable under this Article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses that may be reasonably anticipated from such failure to perform obligations.

ARTICLE II.18 – ACCESS, INSPECTION AND AUDITS

II.18.1. The Contractor, during the currency of the Contract shall, or shall procure that its subcontractors shall gather, compile, correlate, collect and otherwise maintain all relevant accounts, records, books and other information in documentary form or on easily accessible electronic media (“Records”), arising in connection with the performance of the Contract.

II.18.2. In accordance with EMEA’s Financial Regulation, the European Court of Auditors shall be entitled upon reasonable notice to access, inspect and audit the Records held by the Contractor in connection with the performance of the Contract up to five years after the last payment is made to the Contractor by EMEA.

II.18.3. EMEA or an outside body of its choice shall have the same rights as the European Court of Auditors for the purpose of access, inspection and audit of the Records in accordance with Article II.18.2 above.

II.18.4. In addition, the Contractor acknowledges that the European Anti Fraud Office may carry out on-the-spot checks and inspections in accordance with Council Regulation (Euratom, EC) No 2185/96 and Parliament and Council Regulation (EC) No 1073/1999 and agrees to submit thereto.

ARTICLE II.19 – WHOLE AGREEMENT AND AMENDMENTS

This Contract (together with any documents referred to herein and Specific Contract issued hereunder) constitutes the whole agreement between the parties hereto relating to its subject matter and no variations or amendments to the Contract shall be effective unless the subject of a written agreement concluded by the contracting parties. An oral agreement shall not be binding on the contracting parties.

ARTICLE II.20 – SUSPENSION OF THE CONTRACT

Without prejudice to EMEA's right to terminate the Contract, EMEA may at any time and for any reason suspend supply of the Goods, provision of the Services under the Contract, or any part thereof. Suspension shall take effect on the day the Contractor receives notification by registered letter with acknowledgement of receipt or equivalent, or at a later date where the notification so provides. EMEA may at any time following suspension give notice to the Contractor to resume the supply of the Goods or provision of the Services suspended. The Contractor shall not be entitled to claim compensation on account of suspension of the Contract or of part thereof.

SIGNATURES

For the Contractor,
[Company name/forename/surname/title]

For EMEA,
Mr Hans-Georg Wagner, Head of Unit for
Communications and Networking

signature[s]: _____

signature: _____

Done at [place], [date]

Done at London, [date]

In duplicate in English.

ANNEX I TO DRAFT FRAMEWORK CONTRACT - TENDER SPECIFICATIONS (INVITATION TO TENDER NO EMEA/2006/34/PM OF [COMPLETE])

ANNEX II TO DRAFT FRAMEWORK CONTRACT – CONTRACTOR’S TENDER (NO [COMPLETE] OF [COMPLETE])

ANNEX III - SAMPLE SPECIFIC CONTRACT TO FRAMEWORK CONTRACT FOR SUPPLY AND SERVICE

SPECIFIC CONTRACT NO. [complete] TO FRAMEWORK CONTRACT NO.
EMEA/2006/34/PM

European Medicines Agency (hereinafter referred to as "EMA"), which is represented for the purposes of the signature of this contract by Mr Hans-Georg Wagner, Head of Unit for Communications and Networking

of the one part,

and

[official name in full of company]
whose registered address is at [official address in full]

(hereinafter referred to as "the Contractor"), represented for the purposes of the signature of this specific contract by [name in full and title], a duly authorised officer of the Contractor

of the other part,

HAVE AGREED

the following Specific Contract and the following Annexes:

Annex I – Request Form

Annex II – Contractor's Response to the Request Form

Annex III - Deliverables

[Other Annexes]

which form an integral part of this specific contract (the “Specific Contract”).

This Specific Contract implements the framework contract no. [complete] and its Annexes signed by EMA and the Contractor on [complete date] [and renewed/amended on complete date] (the “Framework Contract”).

For the avoidance of doubt, the Contractor acknowledges and agrees that the terms of the Specific Contract and Framework Contract shall apply to the exclusion of the Contractor’s standard terms and conditions.

ARTICLE I.1 - SUBJECT

- I.1.1.** The subject of this Specific Contract is [short description of subject] (the “Goods” and the “Services”).
- I.1.2.** The Contractor undertakes, on the terms set out in the Framework Contract, this Specific Contract and its Annexes, to supply the Goods and provide the Services in accordance with the Request Form (Annex I) and the Contractor’s Response to the Request Form (Annex II) which shall result in the specified deliverables (Annex III).

ARTICLE I.2 - DURATION

- I.2.1.** This Specific Contract shall become effective [on the date on which it is signed by the last contracting party] OR [on specific date]. The supply of the Goods shall take place on [indicate date(s)]. Provision of the Services shall start from [date of entry into force of this Specific Contract] [indicate other date] (“Implementation”).
- I.2.2.** Implementation of this Specific Contract may under no circumstances begin before the date on which the Specific Contract becomes effective.
- I.2.3.** The duration of the Contract shall not exceed [specify duration]. The period allowed for the supply of the Goods and the provision of the Services may be extended only with the express written consent of EMEA before such period elapses.

ARTICLE I.3 – PRICE

The total Charges to be paid by EMEA under the Specific Contract shall be [EUR] [GBP] exclusive of VAT covering all Goods supplied and all Services provided.

Payment shall be made [in advance/in arrears/in arrears upon receipt of all Goods/monthly/other option to complete].

ARTICLE I.4 – AMENDMENTS

No amendment to this Specific Contract shall be effective unless the subject of a written amendment executed by all parties. An oral agreement shall not be binding on either parties.

SIGNATURES

For the Contractor,
[Company name/forename/surname/title]

For EMEA,
Mr Hans-Georg Wagner, Head of Unit for
Communications and Networking

signature[s]: _____

signature:_____

Done at [place], [date]

Done at London, [date]

In duplicate in English.

ANNEX III TO SAMPLE SPECIFIC CONTRACT

Deliverables

Each Specific Contract will have precise deliverables and timelines included in its Annex III.

ANNEX IV TO DRAFT FRAMEWORK CONTRACT – CONDITIONS FOR INFORMATICS (“IT”) CONTRACTS

Article 1 - Quality and standards

- 1.1. The Contractor shall ensure that it performs the Services and provides the Goods in full knowledge and consideration of EMEA's prevailing computing environment. It shall perform the Services and provide the Goods in accordance with technical norms, standards and procedures based on best professional practice in the informatics and/or telecommunications field, and in particular with the ISO 9000 standards.
- 1.2. EMEA shall supply, upon the written consent of the Contractor and without delay, all the assistance, data and information that the Contractor considers reasonably necessary or useful for providing its Goods and Services.
- 1.3. EMEA and the Contractor shall notify each other in writing of any factor likely to impair or delay the proper execution of the Contract immediately upon such circumstances arising or coming to their notice.
- 1.4. The Contractor guarantees that any Goods delivered under this Contract, whether or not developed in execution of this Contract, will not fail to execute their programming instructions due to defects and poor workmanship when properly installed and used on the device(s) designated by the Contractor. They shall be devoid of any deliberate mechanism which leaves it under the Contractor's control after supply to EMEA. They shall meet the operating requirements, specifications and characteristics laid down in this Contract and its Annexes.
- 1.5. The quality of the Contractor's Goods and Services shall be measured by reference to the definitions, quality standards and procedures defined in this Contract or, in default, implied by law. Quality standards may be revised in line with developments on the market at EMEA's absolute discretion.
- 1.6. The Contractor undertakes to comply with those quality standards. Compliance with the standards shall be monitored by EMEA. Unless otherwise stated in the Contract, in the event of non-compliance with one or more of the standards over a sliding period of three (3) months, the Contractor shall submit an improvement plan. In the event of non-compliance with one or more of the standards for three (3) months, consecutive or not, over a sliding period of six (6) months, Goods for which quality has proved substandard may be withdrawn, or the Contract may be terminated where the overall quality of the Services is substandard.
- 1.7. Unless otherwise stated in this Contract, in the event of a complete failure of the combination of Goods and Services to operate together as a system in a way anticipated in this Contract (the “System”) and lasting more than twenty-four (24) hours from the time this state of affairs is notified in writing to the Contractor (“System Failure”), or in the event of intermittent System Failures lasting more than forty-eight (48) hours for any reason whatsoever, the Contractor shall, upon a duly substantiated request, make available to EMEA within twenty-four (24) hours at the most, an equivalent functioning System or the necessary hardware and software enabling EMEA to run its applications in the interim. The cost of such equivalent material shall be charged to the Contractor. If the Contractor can demonstrate that the failure is not attributable to it, it may charge the cost to EMEA at rates to be agreed between EMEA and the Contractor.

Article 2 – Common Technical Provisions

2.1 Security

- 2.1.1. The Contractor's Staff working at the EMEA's office premises must conform to any internal EMEA security rules. If members of the Contractor's Staff are working at the EMEA's office premises, the Contractor shall replace immediately and without any compensation any person considered undesirable by EMEA, at EMEA's request.
- 2.1.2. Any security requirements for individual projects shall be notified by EMEA from time to time or as required.
- 2.1.3. The Contractor agrees to contractually impose the security obligations of this Article upon any of its subcontractors (if applicable) and their staff who perform Services for EMEA in execution of this Contract.
- 2.1.4. The Contractor recognises that no goods, equipment or material whatsoever owned by EMEA or present at EMEA's premises, may be moved or removed without EMEA's express written approval.
- 2.1.5. The Contractor shall take all appropriate steps in relation to all Goods to ensure that the data and the magnetic media upon which they are stored are safely preserved. The Goods supplied shall not contain any mechanism (e.g. including, but not limited to, viruses, etc) which could compromise their proper operation or that of other any other goods or systems at EMEA. The cost of repairing the damage caused by such a mechanism shall be borne entirely by the Contractor.
- 2.1.6. The Contractor undertakes to inform EMEA in writing as soon as it has any knowledge of defaults in its Goods or Services that endanger the security of the configurations of which they may form a part. It shall immediately take any measures necessary to restore the security of the configurations and correct the defaults.
- 2.1.7. The Contractor shall ensure that all security precautions for each of the Goods are clearly identified in the relevant documentation supplied to EMEA and relating to the Goods in question.
- 2.1.8. Should the Contractor need remote access to internal informatics resources from the external domain during the performance of the Services which are the subject of this Contract, it shall be requested to comply with EMEA's internal rules on practical and technical security for remote intervention. This must be achieved by way of signature of a Specific Contract for remote intervention provided by EMEA.

2.2. Specific Intellectual Property Rights

- 2.2.1. As regards all Goods or other protected material or Intellectual Property Rights arising from any Services provided and for which the Intellectual Property Rights are the exclusive property of EMEA or which have been licensed to EMEA by third parties, and which the Contractor is likely to use in the execution of its obligations under this Contract, EMEA expressly authorises the Contractor to use such Goods or other protected material or Intellectual Property Rights, within the limits strictly necessary for the execution of this Contract.

In view of the preceding, the Contractor undertakes:

- not to copy any such Goods or other protected material or Intellectual Property Rights without prior written authorisation from EMEA;
- to use such Goods or other protected material or Intellectual Property Rights exclusively in the context of this Contract;

- to protect and indemnify EMEA against all third-party claims or actions alleging a breach of their Intellectual Property Rights, or a use of such Goods or other protected material or Intellectual Property Rights in contravention with the present Article.

2.2.2. The Contractor undertakes to obtain written consent from EMEA prior to:

- filing a trademark, patent or design application in relation with any of the results or rights obtained in performance of the Contract in its own name or that of a third party;
- claiming a copyright over the results or rights obtained in performance of the Contract in its own name or of that of a third party;
- allowing a third party to do such filings or claims.

Failure to obtain permission from EMEA will entitle EMEA to seek damages against the Contractor and will not prevent EMEA from protecting the rights assigned under this Contract.

2.2.3. The Contractor declares that it is the rightful owner of the Intellectual Property Rights in all Goods and/or the author of the Intellectual Property Rights arising in connection with the provision of the Services delivered under this Contract, and that in relation to the Goods, it is entitled to assign or licence those Intellectual Property Rights in accordance with the terms of this Contract. If those Intellectual Property Rights are the property of third parties, the Contractor guarantees that it has requested and obtained those third parties' written authorisation to grant to EMEA the assignment or licence of their Intellectual Property Rights to the extent as provided under this Contract or necessary to allow EMEA unencumbered use of the Intellectual Property Rights. The Contractor shall be solely responsible for taking the necessary steps, under the laws and regulations in force at the place where the tasks assigned to the Contractor are to be performed, to ensure the opposability to third parties of the assignments or licences granted to EMEA by the Contractor or by such third parties.

2.2.4. The Contractor guarantees that none of the Goods, Services or other protected material delivered, whether or not developed in execution of this Contract, infringes any third party's Intellectual Property Rights.

2.2.5. Each party shall inform the other party of the existence or threat of any third party's action or claim alleging an infringement of its Intellectual Property Rights by EMEA's use of any Goods, Services or other protected material delivered under this Contract, provided such use is made in conformity with the terms of this Contract.

2.2.6. In the event of such a dispute or threat thereof, the Contractor undertakes to conduct all litigation, arbitration or negotiations for settlement, in its own name as well as in EMEA's name, at its own and sole expense.

EMEA agrees to provide the Contractor with all information and assistance that may reasonably be required, at the Contractor's own and sole expense.

However, EMEA reserves the right to decide to conduct its own defence or to negotiate its own settlement, at its own discretion. The Contractor will be responsible for any payment arising out of any settlement or judgment following such a dispute or threat, except for the payment of a settlement made by EMEA without the Contractor's written consent. Such consent may not be withheld without reasonable grounds.

If the infringement of a third party's Intellectual Property Rights is declared in a judgment, arbitration sentence or party settlement, or if such is likely to happen, the Contractor agrees to (1) either procure for EMEA the right to continue using the Goods and its documentation, (2) either replace them with substantially equivalent non-infringing Goods, or, if none of the

foregoing is available, (3) grant to EMEA a credit in the amount corresponding to the purchase price of the proportion of the Goods which can no longer be used.

The Contractor will not be responsible under the present guarantee for any third party claiming an infringement of its Intellectual Property Rights based on (1) EMEA's use of Goods in combination with equipment not delivered by the Contractor, if such combined use is the cause of the claimed infringement, or (2) EMEA's use of any Goods delivered hereunder in a form other than the one delivered by the Contractor, if such change in form is the cause of the claimed infringement.

2.2.7. The guarantee against third party claims afforded by the Contractor to EMEA shall subsist for five (5) years following the end of the Contract, or for five (5) years following the last use by EMEA of the Goods and its documentation delivered by the Contractor, whichever period ends last.

2.3. Co-operation

2.3.1. The Contractor shall assist and advise EMEA on the use of its Goods and Services. It shall be responsible for product integration as regards its inclusion in this Contract, its operation in EMEA's environment and the introduction of new versions.

2.4. Product/Goods developments

2.4.1. Any Goods or Services delivered under this Contract shall have been demonstrated by the Contractor, at its expense, to conform to the technical specifications sent to the Contractor (Annex I).

2.4.2. Any Goods capable of replacing a previously approved product in the same operational environment, with no loss of performance and at no extra cost to EMEA, may be used by the Contractor in the performance of this Contract.

2.4.3. Proposals to include new Goods or Services involving new features or functions not previously available amongst the Goods or Services listed in this Contract shall only be considered in the context of the principal overall specifications covered by the call for tenders (Annex I).

2.4.4. Even if Goods or Services are approved by EMEA, any incompatibility with previous Goods and Services that become apparent in the course of their use shall be resolved by the Contractor as swiftly as possible and at no cost to EMEA.

[2.4.5. Evaluation procedures and trials of new products before inclusion in the price list may be specifically defined in this Contract.]

2.5. Product life or life of Goods

2.5.1. The Contractor shall ensure that the Goods, or similar replacement products, are marketed or available during the lifetime of this Contract from the date of their delivery.

The Contractor shall further ensure that maintenance of the Goods delivered under this Contract may be requested and provided for a period of at least five (5) years from the date of signature of this Contract, or, where applicable, of their certificate of conformity, whichever is the latest.

2.6. Use of Goods

2.6.1. From the date of signature of the consignment note, or, if applicable, of the certificate of conformity, whichever is the latest, EMEA may make unrestricted use of the Goods under

normal operating conditions. EMEA may use the Goods for services it is carrying out for other institutions, agencies or bodies. If the Goods are rented or leased, the right of use applies for the duration specified. If a guarantee applies, maintenance may not start until the guarantee has expired.

2.6.2. The Contractor must ensure that EMEA may add compatible Goods of any origin to a System or connect to it, either directly or via telecommunications networks.

2.6.3. In view of EMEA's supranational nature, the Contractor shall not exert any right of inspection over EMEA's use of the Goods.

2.7. Documentation

The Contractor shall provide EMEA with its documentation and updates, as soon as they become available to its customers, in as many copies, whether in machine-readable form or on paper, as are stated in this Contract or its Annexes. EMEA may reproduce this documentation in full or in part for any internal use by its staff. EMEA shall reproduce all references to Intellectual Property Rights appearing on the originals.

2.8. Benchmarking

EMEA may undertake a process of benchmarking of the levels and the charges of the Goods and Services provided under this Contract by comparison with similar goods and services provided by outsourcing vendors and/or in-house IT service providers and suppliers ("Benchmarking"). The results of such Benchmarking shall be available in identical form to both EMEA and the Contractor.

In order to guarantee that a valid comparison is made, EMEA will ensure that the:

- scope of the Goods and Services being provided by the Contractor is taken into consideration;
- comparison group consists of at least four vendors and/or service providers and suppliers to ensure statistical significance; and
- relevant comparison data must be guaranteed.

The period for Benchmarking shall not exceed four (4) months

For the first Benchmarking exercise, the comparison group shall be defined in a document entitled "Comparison Group Definition". EMEA reserves the right to change the comparison group algorithm to reflect any changes in its business from time to time.

The nominated person carrying out the Benchmarking process on behalf of EMEA (the "Benchmarker") shall be a qualified and objective third party selected by EMEA through a procurement procedure. EMEA will pay all of its own costs and the Benchmarker's costs during the Benchmarking period. The Contractor will pay all of its own costs. Interpretation of the results of the Benchmarking shall be the sole prerogative of the Benchmarker.

EMEA and the Contractor shall set aside sufficient time and resources for each stage of the Benchmarking, such as:

- identification and location of Benchmarking data,
- performing the Benchmarking, and
- implementation of the conclusions of the Benchmarker.

EMEA and the Contractor will be free to suggest changes in Benchmarking parameters as the Goods and Services evolve over the term of this Contract.

The Benchmarking shall treat as confidential all data provided by EMEA and the Contractor, and will return all material and media once the Benchmarking is completed.

If a Benchmarking reveals that the level of a Service does not reach the comparison group's service levels, the Contractor shall immediately prepare an action plan, which will specify all actions necessary to rectify the deviations. The full and measurable implementation of the action plan shall in no circumstances exceed one (1) year. If the Contractor fails to fully implement the action plan, EMEA may claim damages. If a Benchmarking reveals that charges are higher than the comparison group's charges, the Contractor shall immediately reduce its charges to the comparison group level, with effect from the date on which the results of the Benchmarking were delivered to the parties.

Article 3 - Specific Provisions Relating To the Purchase and Rental Of Complex Hardware Goods or Products

3.1. Additional specifications for Hardware Goods Delivery

3.1.1. Terms

All complex hardware Goods shall be tested by the Contractor before their delivery. The Contractor shall be able to demonstrate that the pre-delivery test was satisfactory if EMEA so requests. The number of copies of documentation to be supplied shall be at least one (1) copy per unit of complex hardware Goods, or as requested by EMEA. The Contractor shall notify EMEA in writing of its packaging terms at least two (2) weeks prior to the delivery date provided for in Article I.2 of the Contract (the "Delivery Date"). [The Contractor shall remove all packaging material used during delivery.]

3.1.2. Dates

Failure regarding the Delivery Date is considered a breach of condition of the Contract. Should the Contractor be unable to deliver on the specified Delivery Date, it must then supply equivalent Goods or System with EMEA's prior consent.

Where EMEA has incurred costs vis-à-vis a third party by reason of a delay in delivery or commissioning attributable to the Contractor, then the Contractor shall reimburse those costs upon production of supporting documents, provided that EMEA has notified the Contractor in writing of the risk of incurring damages due to the late delivery soon after having been informed of the Contractor's inability to deliver on time. If a Delivery Date is overrun by more than [forty-five (45)] calendar days, EMEA is entitled to terminate the Contract immediately.

3.1.3. Procedure

The Contractor shall confirm the exact Delivery Date of each consignment of Goods as specified in Articles I.2 and II.1.11 of the Contract.

EMEA shall, during normal working days and hours, provide access to its premises for delivery on the notified Delivery Date. Delivery and installation costs shall be borne by the Contractor. Deliveries shall be complete.

3.2. Goods & Product installation

3.2.1. Installation requirements

For all Goods listed in this Contract, the Contractor shall specify in writing the technical installation requirements and any refurbishment necessary for the premises intended to house the Goods.

EMEA shall ensure that the premises where the Goods are installed satisfy the conditions set out by the Contractor regarding access, air-conditioning and electric power supplies and are equipped with the necessary data transmission lines.

EMEA shall grant the Contractor access to its premises for the assembly of complex hardware Goods on the installation date, which must be duly notified by the Contractor with a means of registered communication within five (5) working days upon EMEA's notification.

3.2.2. Procedure

– Pre-installation meeting

A pre-installation meeting may be organised. A technical representative of the Contractor will be available for a pre-installation meeting organised on EMEA's premises. The purpose of this meeting is to review practical issues related to installation of the Goods. The minutes of each pre-installation meeting should be drafted after the pre-installation meeting by the Contractor, unless otherwise agreed at this meeting.

– Installation

Installation will be done in conformity with this Contract and with the minutes of the pre-installation meeting and in accordance the methodology agreed in the pre-installation meeting if appropriate.

If the place of delivery is not the place of installation, EMEA shall arrange for the Goods to be moved at its own risk from the place of delivery to the place of installation within fifteen (15) working days from the day of signature of the consignment note and undertakes to notify the Contractor of the place of the move in writing within five (5) working days upon successful move of the Goods to the installation site.

3.3. Acceptance

3.3.1. The Commissioning Date

The assembly of complex hardware Goods and the bringing into service of a System shall be executed by the Contractor at its own expense, unless otherwise agreed. The complex hardware Goods or System shall be assembled, installed, and brought into service no later than fifteen (15) working days after the date of notification by EMEA of its removal to the installation site unless another time limit is agreed in writing between EMEA and the Contractor.

Upon successful installation, the Contractor shall notify EMEA by a means of communication of the date on which complex hardware Goods or System have/has been brought into service, which date will be the "Commissioning Date" for the particular Goods or System.

3.3.2. The acceptance period

The acceptance period will run up to seventy-five (75) working days from the Commissioning Date.

During this acceptance period, EMEA shall notify any defaults in the complex hardware Goods or System to the Contractor in writing. As from the date of such notification, the

running of the acceptance period will be suspended up to the date on which the Contractor notifies in writing that it has remedied the notified default, this date will reinitiate the acceptance period for the rest of the [seventy-five (75)] working days period, with a guaranteed minimum period of [twenty-five (25)] working days after the last notification by the Contractor that it has remedied a default.

Upon the expiry of the acceptance period, acceptance of the Goods or System will be recorded in a certificate of conformity that shall indicate inter alia the detailed nature of the accepted complex hardware Goods and the reference number of this Contract. If no certificate of conformity has been issued at the end of the acceptance period and if no notification of faulty operation is pending, EMEA shall be considered as having accepted the complex hardware Goods or System.

3.3.3. Termination

If, due to faulty operation by the Contractor, acceptance cannot be completed within a maximum time limit of [hundred and fifty (150)] calendar days from the Commissioning Date, unless a different time limit has been agreed in writing, EMEA shall be entitled to terminate the Contract after giving the Contractor [thirty (30)] calendar days' notice in writing to meet its obligations.

3.4. Guarantee specifications for complex hardware Goods or Systems

The Contractor shall guarantee all Goods are delivered in conformity with Annex I. During the two-year guarantee period, the Contractor shall provide maintenance at its own and sole expense. The guarantee period shall be automatically extended by the total duration of stoppages attributable to the Contractor during that period, as recorded under the maintenance procedures. For this purpose only stoppages lasting eight (8) consecutive working hours or more shall be counted. One day's extension therefore corresponds to a stoppage of eight (8) consecutive working hours, which may be interrupted by a period of hours not defined as working hours. If failures during the guarantee period are such as to make Goods or the System unusable for an uninterrupted period of more than [one (1) calendar week], EMEA shall be entitled to have the complex hardware Goods and/or System immediately replaced free of charge by the Contractor. If the aggregate unavailability of Goods during normal working hours exceeds forty-eight (48) hours, EMEA is entitled to terminate the part of the Contract relating to these Goods or System.

Article 4 - Specific Provisions Relating to the Purchase of other than complex hardware Goods or System

4.1. Configuration and delivery

4.1.1. Configuration

In respect of each Specific Contract:

- (1) all Goods (including all Goods making up a System) shall be specified;
- (2) installation of all Goods shall be carried out in accordance with the specifications of this Contract.

4.1.2. Delivery

The Delivery Date shall be set at maximum [thirty (30)] calendar days from the date of signature of this Contract, unless a different term has been agreed in writing between the EMEA and the Contractor.

If the Delivery Date is overrun by more than [twenty-one (21)] calendar days, EMEA shall be entitled to terminate the Contract and claim damages thereafter.

A failure regarding the Delivery Date is considered as damage to EMEA. The place of delivery shall be as specified in Article I.2 of the Contract. At the time of delivery, the incoming Goods may be subject to quantitative and qualitative checks by EMEA within five (5) working days. The receipt of each delivery of Goods shall be then recorded in a written consignment note signed by EMEA.

If no certificate of conformity has been issued at the end of the one-month acceptance period and if no notification of faulty operation is pending, EMEA shall be considered as having accepted the complex hardware Goods.

Unless expressly requested by EMEA, partial delivery of a System is not allowed.

4.2. Guarantee specifications for other than complex hardware Goods

The Contractor shall guarantee all Goods delivered for two years.

When other than complex hardware Goods are delivered on several dates, the guarantee period for all the components of the other than complex hardware Goods shall expire with the end of the guarantee period of the final component of the other than complex hardware Goods delivered in accordance with this Contract.

During the two year guarantee period the Contractor shall provide maintenance at its own and sole expense.

Article 5 - Specific Provisions Relating to Licensed Software

5.1. Delivery - installation – Documentation

- 5.1.1. The Delivery Date of the Goods amounting to software (“Software”) shall be set at maximum ten (10) working days from the date of signature of this Contract, unless a different term has been agreed in writing by the parties. A failure concerning the Delivery Date is considered as a breach of condition to EMEA. EMEA may decide to claim the payment of damages only or to terminate the Contract immediately and claim damages thereafter.
- 5.1.2. EMEA shall be permitted to request additional assistance from the Contractor to install the Software on the adequate hardware equipment and for training of its personnel at the time of production start-up. Those additional expenses shall be charged to EMEA.
- 5.1.3. EMEA and the Contractor shall each designate in due time one person each in charge of decisions regarding the delivery and installation of the Software.
- 5.1.4. The manner in which the Software shall be delivered shall be agreed upon writing by the parties.

When it is agreed that the Software shall be delivered as material support, the Software shall be delivered on a machine-readable medium (diskette or other) reproducing the original Software kept in the Contractor's or EMEA's archives. It shall be sent with one copy of its documentation per licensed copy unless agreed otherwise between the parties. Any additional copy of its documentation shall be invoiced to EMEA at the price shown in this Contract. When it is agreed that the Software may be downloaded by EMEA, then the Contractor shall precisely indicate the location of the download area (such as from an area on the Contractor's website, from an FTP site, etc.) and provide EMEA, by a means of communication, with the

accurate and complete instructions, including access codes, enabling it to perform such downloads.

- 5.1.5. Delivery of the Software shall be recorded in a consignment note, presented by the Contractor for signature by EMEA. In the event that the Software is downloaded, EMEA will issue the consignment note based on the communication of the Contractor with the downloading instructions.
- 5.1.6. If no certificate of conformity has been issued at the end of the one-month acceptance period and, if no notification of faulty operation is pending, EMEA is considered as having accepted the Software.
- 5.1.7. The Contractor authorises EMEA to reproduce the documentation for any internal use provided that any copyright indication in the documentation is also reproduced.

5.2. Trial – acceptance

- 5.2.1. Upon the request of EMEA, the Contractor shall grant for each new licensed piece of Software or each new version of the Software a one (1) month trial period during which the Software shall be available for non-productive use. Longer test periods and their conditions may be convened by agreement in writing between the parties.
- 5.2.2. The trial period shall begin on the day of the installation of the Software by the Contractor on the appropriate hardware equipment, or if EMEA does not require installation of the Software by the Contractor, fifteen (15) calendar days after signature of the consignment note.
- 5.2.3. At the end of the trial period, acceptance of the Software shall only result from the signature of a certificate of conformity by both parties. If no certificate of conformity has been issued at the end of the trial period and, if no notification of faulty operation is pending, EMEA shall be considered as having accepted the Software.
- 5.2.4. At any moment during the trial period, EMEA may terminate the testing licence upon notification in writing with immediate effect if the Software does not perform and conform to its description, its specifications or its documentation. Additional acquisitions of Software already tested by EMEA shall be accepted by signature of the consignment note.

5.3. Guarantee specifications for Software

- 5.3.1. The Contractor shall guarantee that the Software delivered is in conformity with the Specifications set out in Annex I.
- 5.3.2. The Contractor warrants that:
 - (1) the documentation is in conformity with the Software supplied;
 - (2) the Software is capable of performing the functions described in the aforementioned documentation and conform to the specifications described in the Specifications set out in Annex I.
- 5.3.3. The Contractor does not warrant that the Software will enable EMEA to achieve any ancillary target aims, productivity levels or time savings not referred to in this Contract or any of its Annexes.
- 5.3.4. Guarantee period

During the two-year guarantee period the Contractor shall provide maintenance at its own and sole expense.

5.4. Use

- 5.4.1. The Contractor hereby grants, and EMEA accepts, a non-exclusive licence to use the Software, under the conditions set hereunder.
- 5.4.2. EMEA may use the Software for its [internal] use.
- 5.4.3. EMEA may acquire "floating licences" for use by external, service-providing companies working under contract on projects for EMEA. At the end of the project, EMEA shall reclaim these licences and may either add them to the existing licence scheme or reallocate them to another company.
- 5.4.4. EMEA undertakes not to reproduce the Software in part or in whole, except for the purposes of back-ups and archives, and after taking all the necessary precautions. Such copies shall remain the Contractor's property.
- 5.4.5. The parties may by this Contract agree that the licence be an exclusive licence for EMEA to use the Software.
- 5.4.6. For the purpose of this Article 5.4., the Software shall be read as including its documentation.

5.5. Compatibility

The Contractor guarantees to EMEA that at the date of signature of this Contract the Software is compatible with all hardware or software described in the Specifications set out in Annex I.

5.6. Escrow rider

- 5.6.1. EMEA and the Contractor may appoint, by mutual agreement, an escrow agent (the "Escrow Agent") who will provide appropriate safekeeping facilities ("Escrow") for the Software and its documentation under separate treaty or rider. If applicable, the Escrow rider shall be concluded between the Contractor, the Escrow Agent and EMEA. The Escrow rider shall provide that the Contractor must deposit with the Escrow Agent a copy of all necessary Software and documentation, source code and that EMEA shall have access to this copy as provided under Article 5.6.2 below.
- 5.6.2. The Escrow rider shall provide that if the Contractor discontinues the maintenance of the Software, EMEA may instruct the Escrow Agent to deliver a copy of the actual source code for the Software involved, including associated control statements required for operation, maintenance and use of the source code, each in programmer-readable form (collectively: the "Source Code"), along with any associated documentation including updates, to the relevant installation site. If EMEA receives the Source Code in the manner provided hereunder, no additional fees shall be charged. Title to the Source Code shall remain with the Contractor.
- 5.6.3. EMEA shall have the right at any time to contact the Escrow Agent for the purpose of confirming the existence of the Source Code and associated documentation including updates thereto and for verification of the instructions to the Escrow Agent to release the Source Code under the circumstances specified under this Article.
- 5.6.4. The Contractor may propose to apply or to enter into a two-party escrow agreement with a third party escrow. In this case, the Contractor shall provide, prior to applying or entering into such agreement, a copy of the proposed agreement to EMEA without charge and all fees in relation to it will be afforded by the Contractor. Should the Contractor fail to provide this copy, EMEA shall be entitled to claim execution of Article 5.6.1.

- 5.6.5. When EMEA considers that the terms of the proposed escrow agreement offer sufficient guarantees to it, it will authorise the Contractor to apply or enter into such agreement with this third party escrow. If EMEA is not entirely satisfied, it may request additional guarantees before authorising the Contractor to enter into the agreement.
- 5.6.6. After having applied or entered into the authorised agreement, the Contractor shall notify EMEA in advance in writing and request its consent for the following:
- the implementation of any change in the terms of this agreement;
 - its termination by the third party escrow;
 - its replacement by a new Contract;
 - a change in third party escrow, or any other change materially affecting the contractual guarantee offered to EMEA.

EMEA may offer its comments and may withhold its consent should it find that the change may result in the absence of the necessary guarantees of access to the Source code within the duration of this Contract.

- 5.6.7. In the event of the escrow agreement being terminated by the third party escrow, or its terms being changed such that the contractual guarantee is materially affected, the Contractor shall immediately notify EMEA of such fact in writing. The Contractor shall then seek a new escrow agreement meeting the requirements of this Article, subject to EMEA's consent prior to the signature of such agreement.
- 5.6.8. Should the Contractor fail to notify EMEA of any change in accordance with the present Article, EMEA shall be entitled to terminate this Contract at the Contractor's expense. EMEA shall also be entitled to seek damages and interest from the Contractor resulting from the Contractor's failure to fulfil its obligations under this Article.

Article 6. - Specific Provisions relating to Maintenance of Goods

6.1. Common provisions

- 6.1.1. Contractual maintenance Services shall commence on the day after expiry of the guarantee period applying to the Goods delivered, unless another date is agreed in writing.
- 6.1.2. The Contractor shall at all times comply with the quality standards and the maintenance security rules contained in this Contract.
- 6.1.3. The maintenance Services shall be provided during normal working hours on normal working days. EMEA may require the Contractor to offer maintenance outside these times ("Extended Working Hours"), and the applicable rates for Extended Working Hours will be specified in the relevant Specific Contract.
- 6.1.4. Maintenance Services are deemed to comprise all operations necessary to maintain the Goods in perfect working order, or to restore defective Goods or one of its components to perfect working order, inclusive of the costs of travelling, parts and labour.

6.2. Maintenance Services

- 6.2.1. Terms

The Contractor undertakes to maintain the Goods covered by this Contract in perfect working order. In order to do this, the Contractor shall at all times have a stock of spare parts or shall obtain the necessary parts at its own and sole expense.

The Contractor shall provide maintenance Services on site within four (4) hours at EMEA's request. This time limit is reduced to two (2) hours in the case of a blocked server. These time limits may be within working hours or other working hours, depending on the choice made in accordance with Article 6.1.3.

If the Contractor is of the opinion that a repair will not be possible within a reasonable repair time from its arrival, it shall make substitute Goods available to EMEA for the duration of the repair.

Repairs, extensions and modifications to the Goods and/or System shall be carried out only by the Contractor or the firms authorised by it.

Preventive maintenance Services shall be scheduled periodically, by agreement between EMEA and the Contractor.

The Contractor shall carry out corrective maintenance Services involving debugging, repair or replacement of faulty Goods at EMEA's request.

The Contractor will formally close each maintenance Service. At the same time it will supply the information needed to measure the quality of the Services and the Goods against the standards laid down in this Contract.

Where computer security has been affected it will submit a report to EMEA.

The Contractor shall compile a monthly management report giving the following particulars of corrective maintenance Services carried out, without prejudice to the relative SLA:

- (1) a list of outstanding problems, with the cause and the expected date of resolution;
- (2) an analysis of problems encountered by type of failure and Goods affected;
- (3) various statistics as requested by EMEA to enable it to produce an internal audit report.

6.2.2. Hardware Goods

On the part of EMEA, hardware maintenance Services shall involve the obligation to use the Goods as specified in the documentation and the installation requirements, and not to alter or repair them itself. On the part of the Contractor, without prejudice to the relative SLA, corrective maintenance Services shall involve:

- (1) diagnosing the cause of failures affecting hardware Goods or the System, whether they are due to its Goods or not;
- (2) correcting faults as rapidly as possible;
- (3) replacing components, printed circuits and electronic units that prove defective in the course of normal use, and effecting any alterations deemed necessary by it to improve operation of the hardware Goods or the System;
- (4) acting as the link with its own central maintenance departments;
- (5) reprogramming or replacing Software in the event of error;

- (6) providing "hot-line" support to resolve urgent problems and System Failures;
- (7) providing drivers for correct function of hardware Goods.

Maintenance Services shall not include the complete repair of all or part of any hardware Goods that are no longer functional as a result of everyday wear and tear. If EMEA decides not to carry out the restoration proposed by the Contractor, the hardware Goods in question will be withdrawn from the Contract.

6.2.3. Software Goods

On the part of EMEA, without prejudice to the relative SLA, maintenance of Software shall involve:

- (1) preparing and sending the Contractor all documents and additional information at its disposal which the Contractor might reasonably request in order to detect and correct errors;
- (2) testing and accepting, when it is reasonable to do so, new versions or new releases of the Software, as proposed by the Contractor. One year after the date of such an acceptance, the Contractor is no longer required to provide maintenance for previous versions or releases of the Software and any other dependent Goods;
- (3) installing any preventive corrections provided by the Contractor as long as it is agreed that such corrections are necessary.

On the part of the Contractor, without prejudice to the relative SLA, maintenance of Software shall involve:

- (1) diagnosing errors or faults encountered by the Contractor or EMEA in the content of the Software and making any necessary corrections; the Contractor shall effect corrections only if the error can be reproduced or if EMEA provides the Contractor with sufficient information from which the error can be diagnosed;
- (2) providing EMEA with successive versions and releases of the Software and the relevant reference documentation; installing new releases and new versions free of charge on the existing hardware at EMEA's request; where necessary, adapting any other Goods and/or System that were using the previous version of the Software, free of charge;
- (3) effecting all corrections (including patches) needed to ensure that the Software and/or System operate as specified in the documentation within thirty (30) working days of receipt of a notification by a means of communication from EMEA giving details of a problem;
- (4) rewriting the Software where necessary so as to correct all known problems or faults diagnosed by the Contractor;
- (5) providing telephone support for EMEA during working hours to advise it on the use of Software;
- (6) providing "hot-line" support to resolve urgent problems with the Software and any related System Failures.

6.2.4. The Contractor undertakes to provide EMEA, upon request, with any remote maintenance service, which it already operates or intends to set up. The remote maintenance service must

comply with the rules set out in the Contract. All terminal connection, utilisation and communication charges shall be borne by the Contractor.

6.2.5. Responsibility for diagnosis

The Contractor has sole responsibility for diagnosing and determining the origin of failures affecting all or part of the System or any Software. As part of this obligation, the Contractor shall, in the event of a diagnosis error, reimburse any costs incurred by EMEA as a result of [needless] corrective action carried out by another supplier.

6.2.6. The expenses due to an intervention of the Contractor necessitated by a serious error or omission of EMEA, PROVIDED it is recognised as such by EMEA, shall be borne by EMEA, according to [the Contractors prevailing standard charges as evidenced by their latest published price list][the conditions and prices in this Contract].

6.2.7. Technical modifications by the Contractor

The Contractor may propose modifications on its own initiative. It will implement them, with EMEA's consent, at times agreed by both parties. These modifications may not entail any additional cost to EMEA or cause any deterioration in performance or loss of function.

6.2.8. Equipment

Test equipment, tools, documents, programs and files kept on EMEA 's premises for maintenance purposes shall remain the property of the Contractor and shall be insured by the Contractor.

Article 7. - Specific Provisions relating to all Informatics Services

7.1. Types of Services

7.1.1. Unless agreed otherwise, the Services shall be provided, both intra muros and extra muros, during EMEA's working hours on EMEA working days.

7.1.2. Training

Services relating to the training and use of the Goods ("Training") should be provided at EMEA's office premises. Training shall be addressed to users of the Goods and to the technicians responsible for support within EMEA. The number of participants for each course shall be determined by mutual agreement between the parties at the time of signature of the relevant Specific Contract. Training and course materials must be available in English.

When Training is provided on EMEA premises, the infrastructure necessary to the courses (buildings, data-processing equipment, video equipment etc.), the administrative organisation of the courses (planning, notifications, and evaluation) and the reproduction of course documentation shall be provided by EMEA.

7.1.3. Consultancy Services relating to the use of the Goods

Consultancy informatics Services consist of transmitting know-how for the use of the Goods covered by this Contract.

7.1.4. Technical Documentation of the Goods

These informatics Services shall relate to the drafting of any technical documentation in relation to the Products covered by the Contract. Technical documentation shall be available in English. It shall be intended for users, both experienced and inexperienced, and for EMEA's

technicians responsible for support or maintenance. The Contractor shall produce the documentation on the basis of the content and structure specifications notified to it by EMEA. Reproduction of documentation shall not form part of the Service.

7.1.5. Integration work

Informatics Services are performed on the basis of integration specifications communicated by EMEA.

7.1.6. Informatics engineering and maintenance

Informatics engineering Services consists of building and implementing projects of data-processing infrastructure (system software, telecommunications networks etc.) and maintenance on the basis of specifications provided by EMEA.

7.1.7. Software development, maintenance and related activities

This consists of the development of Software, maintenance and related activities (e.g. studies, consultancy, documentation, quality assurance etc.) [using the standard EMEA Informatics Architecture], on the basis of specifications provided by EMEA.

7.1.8. Removals

Removals consist of transferring any Goods from one specified place to the other, whether or not within the same building or city. Removals may take place during working hours or Extended Working Hours.

7.1.9. Logistics

Logistics includes but is not limited to, inventory, counting, equipment tagging, security labelling, just-in-time delivery, unpacking and installation in end-user's office.

7.2. Time-and-means Contracts

7.2.1. Services shall be provided on a time-and-means basis when the parties agree that a daily sum is to be paid for a number of days in return for the provision of the means to perform the informatics Services. The sum payable and the nature of the Services will be indicated in the relevant Specific Contract.

7.2.2. At the request of EMEA, the Contractor shall supply all the necessary personal information regarding the Contractor's Staff providing the Services.

7.2.3. Every day during which Services are provided, the Contractor or the Contractor's Staff shall record the time worked. The records shall be set up in the manner defined by EMEA's appointed manager, the name of whom will be notified to the Contractor. At the end of each month, the Contractor or a member of the Contractor's Staff shall complete and sign the attendance sheet proposed by EMEA and forward it to EMEA's appointed manager who shall be in charge of checking the consistency between the daily records and the monthly attendance sheet.

7.3. Quoted time-and-means Contracts.

7.3.1. The "Quoted Time & Means" method may be used for Contractor's Staff outside EMEA premises.

7.3.2. For Quoted Time & Means projects, the work will be ordered for a total number of days and will be divided into various sub-tasks (or "quoted time & means").

- 7.3.3. EMEA will provide the Contractor with a detailed description of each sub-task. The Contractor will then send EMEA an estimate of the number of days needed to carry out the sub-task and the expected Delivery Date.
- 7.3.4. Once the estimate has been accepted by EMEA, only the number of days indicated in the estimate will be chargeable.
- 7.3.5. The invoicing, approved by EMEA, will be carried out on the basis of each sub-task accepted and signed for by EMEA using a specific form.

7.4. Fixed-price Contracts

- 7.4.1. Services shall be provided at a fixed price when the parties agree an overall sum, which must be justified using the agreed daily rates in this Contract, and the sum is paid following express acceptance of the Services by EMEA.
- 7.4.2. The Services shall be undertaken by the Contractor in accordance with the specifications set out in this Contract and its Annexes.
- 7.4.3. Each result and deliverable shall be subject to acceptance by EMEA, in order to ensure conformity with the specifications. The acceptance period will run up to a maximum of seventy-five (75) working days from the day of signature of a consignment note. During this acceptance period, EMEA may notify any defaults in the result or deliverable to the Contractor in writing. As from the date of such notification, the running of the acceptance period will be suspended up to the date on which the Contractor notifies in writing that it has remedied the notified default, which date will reinstate the acceptance period for the rest of the [seventy-five (75)] working days period, with a guaranteed minimum period of [twenty-five (25)] working days after the last notification by the Contractor that it has remedied a default. Upon successful expiry of the acceptance period, EMEA will sign a certificate of conformity for each delivered result or deliverable. If no certificate of conformity has been issued at the end of the acceptance period and no default is pending, EMEA shall be considered as having accepted.

7.5. Stability of Services

- 7.5.1. EMEA and the Contractor shall exchange any information needed for the Services to be provided. Throughout the term of this Contract they shall maintain the required level of information and make it available to the other party for the purpose of providing the Services. The updating of information shall not give rise to any payment.
- 7.5.2. Throughout the term of this Contract the Contractor shall ensure that a stable and consistently high quality of Services is maintained.
- 7.5.3. EMEA must be notified in advance of changes to the Contractor's Staff and reserves the right to refuse them. When a change of Contractor's Staff or a change of Services is unavoidable there should be a ten-day period of adjustment when both the replacement and original personnel should work side by side for training and transfer of relevant information. The costs of this period of adjustment shall be borne by the Contractor.

In no event shall the Contractor be able to plead a change of the Contractor's Staff as a reason for not meeting any of its obligations, in particular with regard to deadlines and quality.

For all Services with a low degree of substitutability, for example project co-ordination, studies and development, the Contractor shall ensure that staff are changed only in the event of force majeure as defined in Article II.12 of the Contract. EMEA must be notified in

advance of any changes proposed to the Contractor's Staff and reserves the right to refuse them.

- 7.5.4. The Services provided on EMEA's premises shall not be supplied by the same persons for more than any maximum period which may be applicable according to EMEA's regulations on non-permanent staff in force at the time of provision of the Services, provided that the initial or renewed duration of the Contract covers that duration.

7.6. Timetable

- 7.6.1. The Contractor shall propose a full and detailed timetable for the development of software Services or related tasks. If such a timetable cannot be prepared for projects of longer duration, the parties shall first fix a provisional timetable. The final timetable shall be fixed at a date stated in the Specific Contract.
- 7.6.2. The time needed by the Contractor to install and prepare the Software or a System for operation shall be stated in the Specific Contract. If no time is specified, the period shall be fifteen (15) calendar days.

Article 8. - Specific Provisions relating to Development and Maintenance of Commissioned Software Goods

8.1. Compliance with technical specifications

When providing the Services of development or maintenance of commissioned Software to EMEA, the Contractor undertakes, in addition to the general quality requirements as specified herein to observe EMEA's "Standard Tools and Methodologies" documentation which outlines EMEA's IT toolset and IT agreed working standards.

Except where expressly stated, the present this Article 8 shall also apply to the development and maintenance of a System commissioned by EMEA.

8.2. Acceptance

- 8.2.1. Software development Services shall be provided in accordance with specifications as agreed upon in writing, and these and the maintenance Services shall be provided in accordance with the following conditions.

- 8.2.2. Delivery of the commissioned software Services, or as the case may be, its different versions, shall be recorded in a consignment note in accordance with Article II.1. of the Contract, presented by the Contractor for signature by EMEA.

- 8.2.3. Acceptance period

The acceptance period will run up to a maximum of [seventy-five (75)] working days from the day of signature of the consignment note. During this acceptance period, EMEA shall notify any defaults in the commissioned software to the Contractor by a means of registered communication. As from the date of such notification, the running of the acceptance period will be suspended up to the date on which the Contractor notifies by a means of registered communication that it has remedied the notified default, which date will reinstate the acceptance period for the rest of the [seventy-five (75)] normal working days period, with a guaranteed minimum period of [twenty-five (25)] normal working days after the last notification by the Contractor that it has remedied a default.

- 8.2.4. The certificate of conformity

Upon the expiry of the acceptance period, acceptance of the commissioned software Services will be recorded in a certificate of conformity, as stated in Article II.1. of the Contract, which

shall indicate inter alia any reservations EMEA may have regarding the commissioned software Services. If no certificate of conformity has been issued at the end of the acceptance period and, if no notification of faulty operation is pending, EMEA shall be considered as having accepted that the commissioned software Services have been satisfactorily completed.

8.2.5. If, after three (3) attempts at acceptance, the commissioned software Services still fail to meet the terms of this Contract, EMEA shall have the following options:

- (1) to require the Contractor to supply, without charge, a replacement commissioned software Services or additional set of software Goods as appropriate;
- (2) to accept part of the commissioned software Services, at a reduced price agreed between EMEA and the Contractor;
- (3) to refuse to accept the commissioned software Services have been supplied satisfactorily and cancel this Contract on reimbursement of any sums previously and duly paid and cancellation of any other sums due or becoming due.

8.3. Guarantee of proper operation of commissioned software Services

8.3.1. Except in the case of hidden defects, for which its liability shall be of unlimited duration, the Contractor shall guarantee the commissioned software Services will be in conformity with the Specifications in Annex I of the Contract. It shall be held responsible for the immediate repair, at its own expense, of any breakdowns that occur during the guarantee period, unless it can prove that such breakdowns have occurred for reasons other than mistakes made in performance of the Services, or other than manufacturing or design errors in that portion of the work for which it was responsible.

8.3.2. EMEA shall notify in writing the Contractor of the type and scale of any failure as soon as it occurs. If the Contractor does not repeat the commissioned software Services without delay, EMEA may have it undertaken by a third party, on the responsibility and at the own and sole expense of the Contractor.

8.3.3. The parties shall jointly define and duly record in minutes the major problems that might affect the commissioned software Services.

8.3.4. The duration of the guarantee shall be extended by the period which elapses between the notification of a major problem to the Contractor duly sent by EMEA during the stated guarantee period and the date at which EMEA accepts the corrected Services.

8.4. Intellectual property rights and ownership of source code

8.4.1. The Contractor hereby assigns to EMEA, which accepts, all Intellectual Property Rights created during the supply of the commissioned software Services, for the entire world, for the entire duration of the Intellectual Property Rights involved, and on an exclusive and definite manner.

8.4.2. EMEA shall become the owner of source code, results, documentation and sets of tests that correspond to payments already made, except when the same relate to pre-existing Software provided. The use of pre-existing Software shall be subject to EMEA's prior written consent.

8.4.3. EMEA shall have the right to disseminate and distribute details of the commissioned software Services to third parties, even if it contains pre-existing Software, subject to observance of any licence terms in respect of third party Software.

8.5. User manuals and Documentation

8.5.1. The Contractor shall prepare the manuals and documentation needed for the appropriate and proper use of the commissioned software Services and shall make them available to EMEA. It shall comply with the provisions under Article 10 below in preparing such manuals and documentation.

8.5.2. The material shall as a rule comprise:

- (1) an installation manual;
- (2) a “Getting Started” manual;
- (3) an administration manual;
- (4) a user manual;
- (5) implementation documentation.

8.5.3. The manuals and the documentation shall be in the file format of the word processing software goods used by EMEA and prepared so that they may be published on EMEA's intranet.

8.5.4. The user manuals and the documentation shall be supplied English.

8.5.5. The Contractor shall update and, if necessary, replace at a reasonable cost the user manuals and documentation files for the maximum duration of the Contract.

8.6. Interfaces and Compatibility

8.6.1. If there are interfaces that need to be observed, the Contractor shall not modify such interfaces without EMEA's written agreement. Such agreement shall not be unreasonably withheld.

8.6.2. Where the commissioned software Services supplied utilise software from a third party and where that software is updated, the Contractor shall adapt the commissioned software Services in accordance with terms jointly agreed.

8.6.3. The Contractor shall ensure that all the commissioned software Services supplied under the Contract are compatible and operate by means of interfaces with all other software utilized by EMEA.

Article 9. - Specific Provisions relating to training organised for EMEA

9.1. Instructors

Instructors shall be proposed to EMEA on the basis of their professional experience and their ability to provide the Services. EMEA must be notified in advance of any changes to agreed instructors and reserves the right to refuse them.

9.2. Organisation of courses

9.2.1. The parties shall draw up a schedule of courses and preparatory measures for a period of several months, normally six (6) months. The schedule shall outline the content of the courses and measures their duration, the dates on which they are to take place, the intended instructors, the number of participants, and the cost.

9.2.2. The parties shall make a final decision on all the schedule no later than four (4) weeks prior to the date on which training is to take place. The Contractor shall then specify the timetables for the courses and shall undertake to adhere to the timetable. If the schedule is disrupted by one or other party, that party shall endeavour to find an equivalent solution.

- 9.2.3. When an instructor is not available, a course may be cancelled or postponed no later than ten working days prior to its commencement. If three courses have been cancelled or postponed without meeting these conditions, EMEA shall be entitled to terminate the Contract pursuant to the provisions under Article II.15.

9.3. Instructor's manual

The Contractor shall comply with EMEA's standard practice as regards:

- (1) the preparation and holding of courses;
- (2) administrative and security regulations;
- (3) health and safety regulations.

9.4. Provision of training Software Goods

- 9.4.1. Training Software that has been developed specifically for EMEA shall be owned in full by EMEA.
- 9.4.2. The provision of training Software shall be covered by a site licence, whose terms shall be consistent with the nature and subject of the training.

Article 10. - Specific Provisions relating to documentation produced for EMEA

- 10.1.1. The Intellectual Property Rights in the documentation that has been developed specifically for EMEA shall belong exclusively to EMEA.
- 10.1.2. The provision of reference documentation shall be covered by a site licence, the terms of which shall be consistent with the nature and subject of the documentation.

ANNEX V TO FRAMEWORK CONTRACT – SERVICE LEVEL AGREEMENT

The Service Level Agreement will be included here.