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OPEN CALL FOR TENDERS

Tender Specifications

“Security and resilience in eHealth Infrastructures and services”

ENISA D-COD-15-T06

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PART 1 INTRODUCTION TO ENISA

1. BACKGROUND ON ENISA

1.1 Introduction

Electronic communications, infrastructure and services are essential factors, both directly and indirectly, in economic and societal development. They play a vital role for society and have in themselves become ubiquitous utilities in the same way as electricity or water supplies, and also constitute vital factors in the delivery of electricity, water and other critical services. Communications networks function as social and innovation catalysts, multiplying the impact of technology and shaping consumer behaviours, business models, industries, as well as citizenship and political participation. Their disruption has the potential to cause considerable physical, social and economic damage, underlining the importance of measures to increase protection and resilience aimed at ensuring continuity of critical services. The security of electronic communications, infrastructure and services, in particular their integrity, availability and confidentiality, faces continuously expanding challenges which relate, inter alia, to the individual components of the communications infrastructure and the software controlling those components, the infrastructure overall and the services provided through that infrastructure. This is of increasing concern to society not least because of the possibility of problems due to system complexity, malfunctions, systemic failures, accidents, mistakes and attacks that may have consequences for the electronic and physical infrastructure which delivers services critical to the well-being of European citizens.

1.2 Scope

The European Union Agency for Network and Information Security (ENISA, hereinafter ‘the Agency’) was established in order to undertake the tasks assigned to it for the purpose of contributing to a high level of network and information security within the Union and in order to raise awareness of network and information security and to develop and promote a culture, of network and information security in society for the benefit of citizens, consumers, enterprises and public sector organisations in the Union, thus contributing to the establishment and proper functioning of the internal market.¹

1.3 Objectives

The Agency’s objectives are as follows:

- The Agency shall develop and maintain a high level of expertise.
- The Agency shall assist the Union institutions, bodies, offices and agencies in developing policies in network and information security.
- The Agency shall assist the Union institutions, bodies, offices and agencies and the Member States in implementing the policies necessary to meet the legal and regulatory requirements of network and information security under existing and future legal acts of the Union, thus contributing to the proper functioning of the internal market.
- The Agency shall assist the Union and the Member States in enhancing and strengthening their capability and preparedness to prevent, detect and respond to network and information security problems and incidents.
- The Agency shall use its expertise to stimulate broad cooperation between actors from the public and private sectors.

2. ADDITIONAL INFORMATION

Further information about ENISA can be obtained on its website: www.enisa.europa.eu.

¹ Regulation (EU) No 526/2013 of the European Parliament and of the Council of 21 May 2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004.

PART 2 TERMS of REFERENCE

A. SCOPE OF THIS TENDER

Within the framework of this Open tender procedure, ENISA would like to find a suitably qualified contractor to provide the services as stipulated in the Terms of Reference outlined below.

Subject of the tender	Maximum budget
Security and Resilience in eHealth Infrastructures and Services	€ 45,000.00
Last date for <u>despatch</u> of offers	26th January 2015

1. GENERAL DESCRIPTION OF THE REQUIRED SERVICES

1.1 CIIP and eHealth

Automation in the area of health care systems has become a need for all patients; medical records, pharmaceutical prescriptions and other health related information convey a large amount of data that it is impossible to maintain and analyse using the old-fashioned ways (paper usage, local copies etc). Tools, systems and infrastructures, have been developed to support this need, offering real-time communication between machines, remote control and “smart” solutions saving lives of citizens. But when it comes to health systems, where the information transferred is sensitive and critical and the systems vital for the well-being of citizens, the issue becomes more complex. Experience shows that now with the wide usage of cloud computing² and big data³, for reasons of elasticity and scalability, the security and privacy concerns rise again this time more prominent than ever.

The European Commission’s Communications⁴ have highlighted the importance of network and information security and resilience for the creation of a single European Information Space. They stress the importance of dialogue, partnership and empowerment of all stakeholders to properly address these threats. The first EU [eHealth Action Plan 2004-2011](#) covered electronic prescriptions and health cards to new information systems that reduce waiting times and errors, in order to facilitate a more harmonious and complementary European approach to eHealth. The second [eHealth Action Plan 2012-2020](#) (see the prior [public consultation](#)) operates in the context of application of patients' rights in cross-border healthcare. It seeks to consolidate the actions that have been addressed to date and take them a step further, in the context of the EU 2020 Strategy and the Digital Agenda for Europe.

On March 30 2009, the European Commission adopted a [Communication on Critical Information Infrastructure protection \(CIIP\)](#) focusing on the protection of Europe from cyber disruptions by enhancing security and resilience. The Communication launched an action plan, involving also Member States and the private sector. It is based on five pillars: (i) preparedness and prevention, (ii) detection and response, (iii) mitigation and recovery, (iv) international cooperation and (v) criteria for European Critical Infrastructures in the field of ICT. Health care systems are considered critical infrastructures.

In its [Conclusions on CIIP of 2011](#) the Council of the European Union stressed the pressing need to make ICT systems and networks resilient and secure to all possible disruptions, whether accidental or intentional; to develop across the Union a high level of preparedness, security and resilience capabilities and to upgrade technical competences to help Europe face the challenge of network and information infrastructure protection; and to foster Member States' cooperation by developing incident cooperation mechanisms between them. As healthcare is a highly regulated sector that encapsulates many legal implications, the challenges on network and information security in these systems cannot be solved following a simple approach.

² <http://www.neurope.eu/article/e-health-next-big-step-cloud-computing>

³ <http://leifhanlen.wordpress.com/2012/11/14/big-data-what-does-it-mean-for-healthcare/>

⁴ “i2010 – A European Information Society for growth and employment1” & “A strategy for a Secure Information Society”,

Health case section is also part of the [proposed NIS directive](#) as one of the critical sectors the provisions of the directive should apply to (risk management and incident reporting), namely health care settings (including hospitals and private clinics) and other entities involved in health care provisions. It is also part of the CIIP objectives in the [national cyber security strategies](#).

ENISA, in this study, would like study for the first time the security challenges and risks of ICT in the health sector in the Member States. By performing this gap analysis and risk assessment, ENISA will be able to draw some early conclusions on common practices followed in the MSs and make recommendations on the next steps (for the regulatory authorities, the public bodies and the EC) towards making more secure and resilient ICT services and infrastructures for eHealth.

2. OBJECTIVES AND TASKS

In the context of this document on eHealth we define all systems and infrastructures that are related to healthcare practice supported by ICTs offered to health professionals and health consumers i.e. tele-medicine, e-pharmacy, e-hospitals. The scope of this study is to identify the security and privacy challenges in these systems and infrastructures; this will be covered under the term cyber security.

The successful contractor is expected to:

- Perform stocktaking of eHealth systems and infrastructures in the EU and their cyber security requirements.
- Collect, analyse and present the results collected on security challenges in eHealth;
- Identify good practices on security challenges in eHealth and draw preliminary recommendations;

The objectives of this tender are organised into the following tasks:

2.1 TASK 1: Stock taking of challenge and risks and analysis

In this task the prospective contractor will need to collect information by performing a desk research of the available literature. The outcome of this task should be a common understanding (common definition) of eHealth, mapping of the different services and infrastructures and assess their criticality thus present the risks and challenges.

The focus of this research will be the use of ICT in eHealth under the scope of cyber security. Material to be reviewed can include relevant existing literature, reports, white papers, national legislation, policies, strategies, initiatives and other research projects (FP7 and STREP) in the EU and also abroad; in parallel, the contractor should identify the most important security risks and challenges in these systems.

In scope are systems used in hospitals, online pharmaceutical provision systems, “smart” ehealth devices and other related to health care information systems. To better understand the security risks and how these are rated per case, the contract should examine the possibility of using use case scenarios; initial ideas for these scenarios could be included in the offer.

In parallel the contractor together with ENISA will identify field experts (involved in building ICT in eHealth, hospital CISOs and CIOs) from public and private and engage them to take part in this study by offering their expertise (participating in survey and/or interviews, validating the results of the study). Examples of stakeholders list should be included in the offer the contractor will submit.

For this task the contractor should:

1. Identify relevant stakeholders from private/ public sector (experts from at least 10 Member States and 5 extra-EU countries) for the interviews/survey and from relevant projects (FP7, national funded projects). (coverage of maximum number of the 28 MSs is not obligatory but recommended);
2. Conduct a desk research on the status of eHealth in the MSs, map and assess the criticality of different systems and infrastructures and list challenges and security risks;
3. Examine the possibility of use case scenarios that would better present the risks in each case (e-hospital, e-pharmacy, smart device etc). Present these use case scenarios.

The outcome of the desk research will be the first milestone of the project. The first intermediate report (R1) will include an initial list of cyber security challenges and risks. It will also include a suggestion of use case scenarios to study the specific risks.

2.2 TASK 2: Questionnaire/ interviews and collection of good practices

In this task the contractor will need to prepare (based on R1) short surveys to collect input from the stakeholders, one survey will include the security risks and how these are rated, and the second one will take stock of the best practices. If needed in some cases, the contractor will have to collect further information through an interview with the stakeholder.

The different challenges should be analysed according to the different eHealth services and infrastructure settings. In this task the contractor will also identify gaps and needs from the stakeholders' input.

For this task the contractor should:

1. Design and implement survey and collect feedback of relevant stakeholders (conducted face-to-face, via telephone or on-line means, etc.) on security challenges in eHealth;
2. Present important risks on ICT in eHealth different setting, based on the validation questionnaire and built on the use cases suggested above;
3. Collect information on good practices in the EU.

The survey and the analysis will be the second milestone of the project. The intermediate report R2 will include the results of this task namely the risks analysis per eHealth setting and a set of common/good practices.

2.3 TASK 3: Recommendations for ICT in eHealth

In this task the contractor should, based on R2, expand the use case scenarios, present the good practices and derive recommendations:

- Support ENISA in validating findings, results, good practices and recommendations with stakeholders;
- Organize or contribute to the organisation of workshops and the drafting of minutes of the workshops;
- Present effectively achieved results by using presentation techniques (paper documents, on-line documents, slides, demonstrators, graphs, videos, etc.);

ENISA will fully support the contractor in the different subtasks. The Contractor will collaborate closely with ENISA throughout the elaboration of the study and agree on the chosen solutions. For this task the contractor should:

1. Finalize the use case scenarios based on the security risks from R1 and R2
2. Draw initial recommendations for the health sector experts, the MSs and the EC.

Deliverable D1 will include the results of this task, and the final document.

2.4 TASK (on-going) Project management

The contractor should implement an appropriate and efficient project management method. The contractor is expected to submit to the agency, prior to the Kick Off meeting, detailed Gantt Charts and related documentation. These will be reviewed by ENISA.

The Gantt charts and related documentation should include:

- Scheduling of all tasks and activities within the tasks,
- Milestones and critical activities,
- Assignment of experts and person days to tasks and activities
- Identification of possible risks and suggestions to mitigate them
- Quality assurance and peer review measures to ensure high quality results

The contractor is expected to send monthly progress reports to the ENISA project manager (template provided by ENISA) about the project and to schedule two-weekly telephone meetings about the progress. The progress reports should include what has been done the previous weeks, the status, what is planned for the next two weeks, the risks and suggested solutions and finally, points to take decisions upon. After meetings, the contractor sends the meeting minutes to the ENISA project manager.

3. EXPECTED SKILLS

The performance of the abovementioned activities requires professionals that have good academic and professional multi- disciplinary knowledge and experience of all or a subset of the following fields:

- Good understanding of Critical ICT Infrastructures Protection, at both policy and operational levels
- Proven experience in projects of similar topic on e-health in regional, national, European, international level.
- Proven experience in organising stock taking exercises, analysis skills, and creating good practice guides and recommendations on relevant subjects
- Excellent knowledge of data collection and validation methods including the ability to produce clear and understandable text equipped with graphical elements
- Good professional experience in relevant information security issues and disciplines (e.g. security policies and controls)
- Good understanding of policy and regulatory issues related to the security of public telecommunication networks at national and/or pan European level including activities related to Critical Information Infrastructure Protection (CIIP)

- Excellent project management skills including quality assurance
- Very good communication skills

4. DURATION AND DEADLINES

The scheduled duration of the contract is for a maximum of 7.5 months and the contractor must be available to start March 2015.

1. Kick off meeting – no later than 10th of March 2015
2. Intermediate deliverable R1 – no later than 20th of April 2015
3. Intermediate deliverable R2 – no later than 1st of July 2015
4. Deliverable D1 – no later than 1st of September 2015
5. Final delivery - no later than 15th of October 2015

The deliverable shall include the full report, a slide show and a presentation for the ENISA staff delivered online.

5. LIST OF DELIVERABLES

The final deliverables should use the standard ENISA document template, which will be provided to successful contractor.

The following milestones and deliverable are expected:

- Intermediate report 1 (R1): Desk research and risks analysis
- Intermediate report 2 (D2): Risks rating and collection of good practices
- Deliverable 1 (D1): Use case scenarios and recommendations
- FINAL DELIVERABLE (FD): The full report.

English is the language to be used for all the documents (interim and final reports, project management reports etc.) produced.

6. PLACE OF EXECUTION OF THE ACTIVITIES AND COMMUNICATIONS

The execution of the activities will take place at the Contractor's premises. Network based collaborative tools (i.e. videoconferencing) will be used as working methods. No physical meetings are envisaged for this project.

It should be mentioned that the costs of potential business trips –if any was needed- should be included in the total offer. ENISA will not additionally reimburse the contractor for taking part in these meetings.

7. TENDER RESULT AND ESTIMATED CONTRACT VALUE

The result of the evaluation of tenders will be the awarding of a Service Contract. The total estimated budget cannot exceed **45,000.00 Euros (forty five thousand Euros)** covering all tasks executed and including all costs (e.g. travelling expenses of the contractor to and from ENISA's premises).

8. CONTENT AND PRESENTATION OF THE TECHNICAL OFFER

The Tenderer shall enclose with the **Technical Offer** all documents and information that will enable its offers to be assessed in terms of quality and of compliance with the Specifications. An Offer shall include a description of the operational means and procedures to be implemented to perform the Contract, supported where appropriate by related documents.

An offer must address each of the following elements as A MINIMUM in order to be considered to be a valid and conforming offer:

- Description of the skills of the prospective contactor
 - The Tenderer will have to present its compliance with the expected skills as described in the relevant section.
- Description of the deliverables
 - The deliverables must be presented as requested in the article entitled “Deliverables”
 - The approach and method to perform the tasks and ensure the quality of the deliverables (stakeholders involved, reasoning behind, interesting use cases to study, reasoning why etc.).
 - Examples of previous related works, specifically on: gap analysis, ehealth projects, and critical information infrastructures protection projects.
 - A full list of all related projects and activities that the contractor has undertaken in the past.
- The prospective contractor is expected to provide insights in the methodology (approach) chosen in order to reach the objectives of the project described above in article “Objectives and tasks”. In particular:
 - Details need to be provided how the experts and stakeholder opinions and needs would be collected (what stakeholder groups involved, means by which the input will be gathered) both for both reports.
- Management of provision of services
 - Project Management: a close description of the project management method used including quality assurance is required. Breakdown of tasks; milestones definition; assignment of experts to tasks and person days to tasks should be presented in a Gantt chart, included in the offer
 - At the kick off meeting, the project plans will be confirmed as final
 - The prospective contactor must also identify possible risks to the project and propose mitigation measures
 - interact with ENISA staff and external experts, and provide regular management reporting. This will ensure the punctual delivery of good quality results of this project and on budget
- In addition the tenderer is expected to highlight / explain
 - Availability and ability of the tenderer to respond: prompt availability of resources is required within the specified delivery timeframes. Additionally, any ancillary or support resources, such as a network of associates to support the scope of this Call for Tenders must be clearly stated

- Short CV's of the experts that will be allocated to the project focussing on their experience and expertise in the areas covered by the study.
- If applicable, the contractor should also provide justification for subcontracting,

9. CONTENT AND PRESENTATION OF THE PRICE OFFER

The Price offer must be drawn up using the Financial Offer template provided (see Annex IV).

10. PRICE

Prices submitted in response to this Tender must be inclusive of all costs involved in the performance of the contract. Prices shall be submitted only in Euro and VAT excluded.

11. PRICE REVISION

Prices submitted in response to this Tender shall be fixed and not subject to revision.

12. COSTS INVOLVED IN PREPARING AND SUBMITTING A TENDER

ENISA will not reimburse any costs incurred in the preparation and submission of a Tender. Any such costs must be paid by the Tenderer.

13. PERIOD OF VALIDITY OF THE TENDER

Tenderers must enclose a confirmation that the prices given are valid for (90) ninety days from the date of submission of the tender.

14. PROTOCOL ON PRIVILEGES AND IMMUNITIES OF THE EUROPEAN COMMUNITIES

ENISA is exempt from all taxes and duties, including 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.

15. PAYMENT ARRANGEMENTS

Payments under the Contract shall be carried out within 60 days of submission of an invoice accompanying the final report or deliverable based on the conditions set out in the draft contract. One single payment will be made after receipt and approval of the deliverables by ENISA. An invoice must specify the specific deliverables covered. A note that accompanies the final deliverables must present the resources used for each of the deliverables presented. Time sheets should be submitted as appropriate.

16. CONTRACTUAL DETAILS

A model of the Service Contract is proposed to the successful candidate - see Annex V.

Please note that the general conditions of our standard service contract cannot be modified. Submission of a tender by a potential contractor implies acceptance of this contract and all of the terms and conditions contained therein. It is strongly recommended that you have this draft contract checked and passed by your legal section before committing to submitting an offer.

PART 3 TENDER SPECIFICATIONS

1. FORMAL REQUIREMENTS

1.1 Address and deadline for submission of the Tender:

You are invited to tender for this project and requested to submit your tender no later than **26th January 2015** either by:

- a) **Registered post or express courier**. The postal service's dated stamp or the courier company's printed delivery slip and stamp will constitute proof of compliance with the deadline given above:

or

- b) **Hand-delivery** (direct or through any authorised representative of the Tenderer) by 17.00 hours on **26th January 2015** at the latest to the address shown below (please, be informed that only delivery during working hours 09:00-17:00 hrs. is accepted). In the case of hand-delivery, in order to establish proof of the date of deposit, the depositor will receive from an official at the below-mentioned address, a receipt which will be signed by both parties, dated and time stamped.

Please note that in this case it is the date and time actually received at the ENISA premises that will count.

Please Note: Due to frequent delays encountered with the postal services in Europe, we would ***strongly suggest that you use a courier service***. It is important to avoid delays to the programmed Opening and Evaluation dates as this will in turn delay the contract award, thereby affecting project completion dates.

The offer must be sent to one of the following addresses:

Postal Address		Express Courier & Hand Delivery
European Union Agency for Network and Information Security (ENISA) For the attention of: The Procurement Officer PO Box 1309 71001 Heraklion Greece	or	European Union Agency for Network and Information Security (ENISA) For the attention of The Procurement Officer Science and Technology Park of Crete (ITE) Vassilika Vouton 70013 Heraklion Greece

Please note that late despatch will lead to exclusion from the award procedure for this Contract.

1.2 Presentation of the Offer and Packaging

The offer (consisting of one original and two copies) should be enclosed in two envelopes, both of which should be sealed. If self-adhesive envelopes are used, they should be further sealed with adhesive tape, upon which the Tenderer's signature must appear.

The **outer envelope**, in addition to the above-mentioned ENISA address, should be addressed as follows:

<p>OPEN CALL FOR TENDER NO. ENISA D-COD-15-T06</p> <p>“Security and resilience in eHealth infrastructures and services”</p> <p>NOT TO BE OPENED BY THE MESSENGER/COURIER SERVICE</p> <p>NOT TO BE OPENED BY THE OPENING COMMITTEE BEFORE 5th FEB 2015</p> <p>TENDERED BY: <YOUR COMPANY NAME></p>
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The **inner envelope** should be addressed as follows:

<p>OPEN CALL FOR TENDER NO. ENISA D-COD-15-T06</p> <p>“Security and resilience in eHealth infrastructures and services”</p> <p>NOT TO BE OPENED BY THE OPENING COMMITTEE BEFORE 5th FEB 2015</p> <p>TENDERED BY: <YOUR COMPANY NAME></p>

1.3 Identification of the Tenderer

Tenderers are required to complete the **Legal Entity Form (Annex I)** which must be signed by a representative of the Tenderer authorised to sign contracts with third parties. There is one form for 'individuals', one for 'private entities' and one for 'public entities'. A standard form is provided for each category - please choose whichever is applicable. In addition to the above, a **Financial Identification Form** must be filled in and signed by an authorised representative of the Tenderer and his/her bank (or a copy of the bank account statement instead of bank's signature). A specimen form is provided in **Annex II**. Finally a **Declaration by Authorised Representative (Annex VI)** must also be completed for internal administrative purposes.

The **Legal Entity Form** must be supported by the following documents relating to each Tenderer in order to show its name, address and official registration number:

a) For private entities:

- A legible copy of the instrument of incorporation or constitution, and a copy of the statutes, if they are contained in a separate instrument, or a copy of the notices of such constitution or incorporation published in the national or other official journal, if the legislation which applies to the Tenderer requires such publication.
- If the instruments mentioned in the above paragraph have been amended, a legible copy of the most recent amendment to the instruments mentioned in the previous indent, including that involving any transfer of the registered office of the legal entity, or a copy of the notice published in the relevant national or other official journal of such amendment, if the legislation which applies to the Tenderer requires such publication.
- If the instruments mentioned in the first paragraph have not been amended since incorporation and the Tenderer's registered office has not been transferred since then, a written confirmation, signed by an authorised representative of the Tenderer, that there has been no such amendment or transfer.
- A legible copy of the notice of appointment of the persons authorised to represent the Tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation which applies to the legal entity concerned requires such publication.
- If the above documents do not show the registration number, a proof of registration, as prescribed in their country of establishment, on one of the professional or trade registers or any other official document showing the registration number.
- If the above documents do not show the VAT number, a copy of the VAT registration document, where applicable.

b) For Individuals:

- A legible copy of their identity card or passport.
- Where applicable, a proof of registration, as prescribed in their country of establishment, on one of the professional or trade registers or any other official document showing the registration number.
- If the above documents do not show the VAT number, a copy of the VAT registration document, where applicable.

c) For Public Entities:

- A copy of the resolution decree, law, or decision establishing the entity in question or failing that, any other official document attesting to the establishment of the entity.

All tenderers must provide their Legal Entity Form (Annex I) as well as the evidence mentioned above.

In case of a joint bid, only the co-ordinator must return the Financial Identification form (Annex II).

The Tenderer must be clearly identified, and where the Tender is submitted by an organisation or a company, the following administrative information and documents must be provided: Full name of organisation/company, copy of legal status, registration number, address, person to contact, person authorised to sign on behalf of the organisation (copy of the official mandate must be produced), telephone number, facsimile number, VAT number, banking details: bank name, account name and number, branch address, sort code, IBAN and SWIFT address of bank: a bank identification form must be filled in and signed by an authorised representative of each Tenderer and his banker.

Tenders must be submitted individually. If two or more applicants submit a joint bid, one must be designated as the lead Contractor and agent responsible.

1.4 Participation of consortia

Consortia, may submit a tender on condition that it complies with the rules of competition. The 'Consortium Form' (Annex VII) must be completed and submitted with your offer.

A consortium may be a permanent, legally-established grouping or a grouping which has been constituted informally for a specific tender procedure. Such a grouping (or consortia) must specify the company or person heading the project (the leader) and must also submit a copy of the document authorising this company or person to submit a tender. All members of a consortium (i.e., the leader and all other members) are jointly and severally liable to the Contracting Authority.

In addition, each member of the consortium must provide the required evidence for the exclusion and selection criteria (*Articles 2 and 3 below*). Concerning the selection criteria "technical and professional capacity", the evidence provided by each member of the consortium will be checked to ensure that the consortium as a whole fulfils the criteria.

The participation of an ineligible person will result in the automatic exclusion of that person. In particular, if that ineligible person belongs to a consortium, the whole consortium will be excluded.

1.5 Subcontracting

In well justified cases and subject to approval by ENISA, a contractor may subcontract parts of the services. The 'Sub-contractors Form' (Annex VIII) must be completed and submitted with your offer.

Contractors must state in their offers what parts of the work, if any, they intend to subcontract, and to what extent (% of the total contract value), specifying the names, addresses and legal status of the subcontractors.

The sub-contractor must not sub-contract further.

Sub-contractors must satisfy the eligibility criteria applicable to the award of the contract. If the identity of the intended sub-contractor(s) is already known at the time of submitting the tender, all sub-contractors must provide the required evidence for the exclusion and selection criteria.

If the identity of the sub-contractor is not known at the time of submitting the tender, the tenderer who is awarded the contract will have to seek ENISA's prior written authorisation before entering into a sub-contract.

Where no sub-contractor is given, the work will be assumed to be carried out directly by the bidder.

1.6 Signatures of the Tender

Both the technical and the financial offer must be signed by the Tenderer's authorised representative or representatives (preferably in blue ink).

1.7 Total fixed price

A total fixed price expressed in Euro must be included in the Tender. The contract prices shall be firm and not subject to revision.

1.8 Language

Offers shall be submitted in one of the official languages of the European Union (preferably in English).

1.9 Opening of the Tenders

The public opening of received tenders will take place on **5th February 2014 at 10:00am** at ENISA Building, Science and Technology Park of Crete, GR - 70013 Heraklion, Greece.

A maximum of one legal representative per participating tenderer may attend the opening session. Tenderers shall inform the Agency in writing of their intention to attend, at least 48 hours prior to the opening session.

2. GROUNDS FOR EXCLUSION OF TENDERERS

2.1 Reasons for Exclusion

In line with Articles No.106, 107, 109(1) of the European Parliament and of the Council Regulation No 966/2012 of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002; candidates or tenderers shall be excluded from participation in a procurement procedure if:

- a) They are bankrupt 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
- b) Are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- c) They have been convicted of an offence concerning their professional conduct by a judgement which has the force of res judicata;

- d) They have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- e) 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;
- f) They have been the subject of a judgement which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- g) 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.

Tenderers must certify that they are not in one of the situations listed in point 2.1 (see Annex III: Exclusion criteria and non-conflict of interest form). If the tender is proposed by a consortium this form must be submitted by each partner.

2.2 Other reasons for not awarding the Contract

Contracts may not be awarded to Candidates or Tenderers who, during the procurement procedure:

- a. Are subject to a conflict of interest;
- b. Are guilty 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;
- c. Any attempt by a Tenderer to obtain confidential information, enter into unlawful agreements with competitors or influence the evaluation committee or ENISA during the process of examining, clarifying, evaluating and comparing tenders will lead to the rejection of his offer and may result in administrative penalties.

See last paragraph point 2.1.

2.3 Confidentiality and Public Access to Documents

In the general implementation of its activities and for the processing of tendering procedures in particular, ENISA observes the following EU regulations:

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;
- Regulation (EC) No. 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data;

- Regulation (EC) No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

3. SELECTION CRITERIA

The following criteria will be used to select the Tenderers. If the Tender is proposed by a consortium these criteria must be fulfilled by each partner.

Documentary evidence of the Tenderers' claims in respect of the below-mentioned criteria is required.

3.1 Professional Information

The Tenderer must provide evidence of enrolment (declaration or certificates) in one of the professional or trade registers, in country of establishment.

3.2 Financial and Economic Capacity

Proof of financial and economic standing shall be furnished by the following documents and minimum requirements:

- a) Copy of the financial statements (balance sheets and profit and loss accounts) for the last two (2) financial years for which accounts have been closed, where publication of the accounts is required under the company law of the country in which the economic operator is established. In case of a consortium, each consortium member shall present their financial statements.

If the tenderer is not obliged to publish its accounts under the law of the state in which it is established, a copy of audited accounts for the last two (2) financial years should be presented. In case of a consortium, audited accounts for each consortium partner shall be presented.

- b) A statement of the average turnover of the last two (2) financial years for which accounts have been closed.
- c) If tenderers will call on the competences of another entity (for example, a parent company), a written undertaking by the said entity certifying that it will make available to the tenderers the resources required to implement the contract.

If for some exceptional reason which the Contracting Authority considers justified, the tenderer is unable to provide the documentary evidence requested above, he may prove his economic and financial capacity by any other means which the Contracting Authority considers appropriate, but only following a request for clarification before the tender expiry date.

3.3 Technical and professional capacity

Evidence of the technical and professional capacity of the tenderers shall be furnished on the basis of the following documents:

- A curriculum vita of the Tenderer, as well as of all members of the Tenderer's team, shall be included, in which the Tenderer shall refer to the skills and experience required (in line with Part 2 – Art 3 - Expected Skills):
- Their technical knowledge and experience in the relevant technical areas (including references to projects similar to the one proposed in this tender);
- Their management capability (including, but not limited to, project management in a European context and quality assurance).

4. AWARD CRITERIA

4.1 Quality of the Offer

Once the Tenderer has demonstrated the appropriate capacity to perform the Contract on the grounds of the selection criteria, the offer will be assessed on the basis of the award criteria.

No	Qualitative award criteria		Weighting (max. points)
1.	Technical compliance	Compliance with the technical descriptions (Part 2 of this document)	25
2.	Quality and accuracy of content and structure	Quality of the proposal and accuracy of the description to provide the requested services	30
3.	Project Team	Composition of project team (ratio senior/juniors), relevant experience of the team, work flows and review cycles of the output, direct involvement of senior staff, and distribution of tasks amongst experts; quality reviews of deliverables.	25
4.	Methodology	Selected methodology and project management	20
Total Qualitative Points (QP)			100

Minimum attainment per criterion

Offers scoring less than 50% for any criterion will be deemed to be of insufficient quality and eliminated from further consideration.

Minimum attainment overall

Offers scoring less than 60% after the evaluation process will be considered to be of insufficient quality and eliminated from the following phase.

The sum of all criteria gives a total of 100 points. The respective weighting between the different awards criteria depends on the nature of the services required and is consequently closely related to the terms of reference. The award criteria are thus quantified parameters that the offer should comply with. The **qualitative award criteria** points will be weighted at **70%** in relation to the price.

4.2 Price of the Offer

Tenders must state a total fixed price in Euro. Prices quoted should be exclusive of all charges, taxes, dues including value added tax in accordance with Article 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities. Such charges may not therefore be included in the calculation of the price quoted.

ENISA, in conformity with the Protocol on the Privileges and Immunities of the European Community annexed to the Treaty of April 8th, 1965, is exempt from all VAT.

Offers exceeding the maximum price set in Part 2; Article 7 will be excluded. The cheapest offer will receive the maximum points and the rest of the candidate's offers will be awarded points in relation to the best offer as follows

$$PP = (PC / PB) \times 100$$

Where;

- PP** = Weighted price points
- PC** = Cheapest bid price received
- PB** = Bid price being evaluated

5. AWARD OF THE CONTRACT

The contract for each Lot will be awarded to the offer which is the most cost effective (offers the best value for money) which obtains the highest number of points after the final evaluation on the basis of the ratio between the **quality criteria (70%) and the price (30%)**. The following formula will be used:

$$TWP = (QP \times 0.7) + (PP \times 0.3)$$

Where;

- QP** = Qualitative points
- PP** = Weighted price points
- TWP** = Total weighted points score

In case the successful tenderer is unable to sign the contract for any reasons, the Contracting Authority reserves the right to award the contract to other tenderers as per the ranking order established following the evaluation procedure.

6. PAYMENT AND STANDARD CONTRACT

Payments under the Service Contract shall be made in accordance with article I.5 of the Special Conditions and article II.4.3 of the General Conditions (see Annex V)

In drawing up their bid, the Tenderer should take into account the provisions of the standard contract which include the “General terms and conditions applicable to contracts”

7. VALIDITY

Period of validity of the Tender: 90 days from the closing date given above. The successful Tenderer must maintain its Offer for a further 220 days from the notification of the award.

8. LOTS

This Tender is not divided into Lots.

9. ADDITIONAL PROVISIONS

- Changes to tenders will be accepted only if they are received on or before the final date set for the receipt of tenders.
- Expenses incurred in respect of the preparation and presentation of tenders cannot be refunded.
- No information of any kind will be given on the state of progress with regard to the evaluation of tenders.
- All documents submitted by Tenderers will become property of ENISA and will be regarded as confidential.

10. NO OBLIGATION TO AWARD THE CONTRACT

Initiation of a tendering procedure imposes no obligation on ENISA to award the contract. Should the invitation to tender cover several items or lots, ENISA reserves the right to award a contract for only some of them. ENISA shall not be liable for any compensation with respect to Tenderers who's Tenders have not been accepted. Nor shall it be so liable if it decides not to award the contract.

11. DRAFT CONTRACT

A Service Contract will be proposed to the selected candidate. A draft copy of which is included as Annex V to this tender.

Please note that the general conditions of our standard service contract cannot be modified. Submission of a tender by a potential contractor implies acceptance of this contract and all of the terms and conditions contained therein. It is strongly recommended that you have this draft contract checked and passed by your legal section before committing to submitting an offer.

12. SPECIFIC INFORMATION

12.1 Timetable

The timetable for this tender and the resulting contract(s) is as follows:

Title: **“Security and resilience in eHealth infrastructures and services”**

ENISA D-COD-15-T06

Summary timetable comments

Launch of tender - Contract notice to the Official Journal of the European Union (OJEU)	05 December 2014	
Deadline for request of information from ENISA	22 January 2015	
Last date on which clarifications are issued by ENISA	23 January 2015	
Deadline for submission of offers	26 January 2015	in case of hand-delivery (17:00 local time. This deadline is fixed for the receipt of the tender in ENISA's premises)
Opening of offers	5 February 2015	At 10:00 Greek time
Date for evaluation of offers	5 February 2015	At 10:30 Greek time
Notification of award to the selected candidate and 10 day standstill period commences	Mid February 2015	Estimated
Contract signature	Late February 2015	Estimated
Commencement date of activities	As per tender	Estimated
Completion date of activities	As per tender	Estimated

ANNEX I

Legal Entity Form

The specific form, for either a;

- c) public entity,
- d) private entity or
- e) individual entity,

is available for download in each of the 22 official languages at the following address: http://ec.europa.eu/budget/execution/legal_entities_en.htm

Please download the appropriate form, complete the details requested and include in your tender offer documentation.

ANNEX II

FINANCIAL IDENTIFICATION FORM

- SPECIMEN FOR THE TENDERER -

(to be completed by the Tenderer)

The Tenderer's attention is drawn to the fact that this document is a sample only, and a specific form in each of the 23 official languages is available for download at the following address:

http://ec.europa.eu/budget/execution/ftiers_en.htm

	
FINANCIAL IDENTIFICATION	
PRIVACY STATEMENT	http://ec.europa.eu/budget/library/contracts_grants/info_contracts/privacy_statement_en.pdf
ACCOUNT NAME	
ACCOUNT NAME 	<input type="text"/> <input type="text"/>
ADDRESS	<input type="text"/> <input type="text"/>
TOWN/CITY	<input type="text"/>
POSTCODE	<input type="text"/>
COUNTRY	<input type="text"/>
 <i>The name or title under which the account has been opened and not the name of the account holder</i>	
CONTACT	<input type="text"/>
TELEPHONE	<input type="text"/>
FAX	<input type="text"/>
E-MAIL	<input type="text"/>
BANK	
BANK NAME	<input type="text"/> <input type="text"/>
BRANCH ADDRESS	<input type="text"/> <input type="text"/>
TOWN/CITY	<input type="text"/>
POSTCODE	<input type="text"/>
COUNTRY	<input type="text"/>
ACCOUNT NUMBER	<input type="text"/>
IBAN 	<input type="text"/>
 <i>If the IBAN Code (International Bank Account Number) is applied in the country where your bank is situated</i>	
REMARKS:	<input type="text"/>
BANK STAMP • SIGNATURE OF BANK REPRESENTATIVE (Both obligatory) 	DATE • SIGNATURE OF ACCOUNT HOLDER (Obligatory)

ANNEX III

DECLARATION OF HONOUR ON EXCLUSION CRITERIA AND ABSENCE OF CONFLICT OF INTEREST

(Complete or delete the parts in grey italics in parentheses) [Choose options for parts in grey between square brackets]

The undersigned (*insert name of the signatory of this form*):

in [his][her] own name (*for a natural person*)

or

representing the following legal person: (*only if the economic operator is a legal person*)

Full official name:

Official legal form:

Full official address:

VAT registration number:

➤ declares that [*the above-mentioned legal person*][he][she] is not in one of the following situations:

a) is bankrupt or 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;

b) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;

c) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;

d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;

e) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the Union's financial interests;

➤ is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the Union's budget.

➤ (*Only for legal persons other than Member States and local authorities, otherwise delete*) declares that the natural persons with power of representation, decision-making or control⁵ over the above-mentioned legal entity are not in the situations referred to in b) and e) above;

➤ declares that [*the above-mentioned legal person*][he][she]:

⁵ This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

- g) has no 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 affinity, family, emotional life or any other shared interest;
- h) will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) 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 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 award of the contract;
- j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure ;

➤ acknowledges that *[the above-mentioned legal person][he][she]* may be subject to administrative and financial penalties⁶ if any of the declarations or information provided prove to be false.

In case of award of contract, the following evidence shall be provided upon request and within the time limit set by the contracting authority:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

If the tenderer is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

.....
Full name

.....
Signature

.....
Date

⁶ As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

ANNEX IV

FINANCIAL OFFER:

“Security and resilience in eHealth infrastructures and services”

ENISA D-COD-15-T06

Please provide your financial lump sum offer.

Project Description:	Number of 'Person days' required for completion of project.	Your OFFER
Security and resilience in eHealth infrastructures and services <i>Please provide your lump sum price for the total deliverables.</i>	P/Days	€

I the tenderer declare that this Financial Offer form has been completed without leaving any box blank.

Print name:
(of the Tenderer or authorised representative)

Signature:

Date:

ANNEX V

Model Service Contract template

(See attached file)

ANNEX VI
ADMINISTRATIVE IDENTIFICATION AND DECLARATION FORM:

IDENTIFICATION OF THE TENDERER	
Name of Tenderer <i>(in full)</i>	
Legal form of Tenderer <i>(e.g. SA)</i>	
Date and country of registration	
Registration number	
VAT number	
Registered office address	
Administrative address (if different to above)	
Name of contact person	
Position <i>(e.g. Manager)</i>	
Telephone number	
e-mail address	
Website	

DECLARATION BY AUTHORISED REPRESENTATIVE OF TENDERER ⁷	
<i>I, the undersigned, certify that the information given in this tender is correct & that the tender is valid.</i>	
First name	
Last name	
Title <i>(e.g. Mr, Mrs, Dr, Professor.)</i>	
Position <i>(e.g. Director)</i>	
Telephone number	
e-mail address	

SIGNATURE: **DATE:**

⁷ Must be a legally constituted representative of the tendering entity otherwise the tender signature is invalid

ANNEX VII Consortium form

Name of tenderer:

Form of the Consortium: (Please cross the relevant box)

Permanent: Legally established: Specifically for this tender:

	Name(s)	Address
Leader of the Consortium <i>(person authorised to conclude contract)</i>		
Partner 1*		
Partner 2*		

* add additional lines for partners if required. **Note that a subcontractor is not considered to be a partner.**

We confirm, as a partner in the consortium, that all partners are jointly and severally liable by law for the performance of the contract, that the leader is authorised to bind, and receive instructions for and on behalf of, each partner, that the performance of the contract, including payments, is the responsibility of the leader, and that all partners in the consortium are bound to remain in the consortia for the entire period of the contract's performance.

Signature: <i>Leader of consortium</i>	
Date:	
Signature: <i>Partner 1</i>	
Date:	
Signature: <i>Partner 2...etc</i>	
Date:	

ANNEX VIII Sub-contractors form

	Name(s)	Address
Tenderer (person authorised to sign contract)		
Sub-contractor 1*		
Sub-contractor 2*		

* add additional lines for subcontractors if required.

As subcontractors for this tender, we confirm that we are willing to perform the tasks as specified in the tender documentation.

Signature: <i>Tenderer</i>	
Date:	
Signature: <i>Subcontractor 1</i>	
Date:	
Signature: <i>Subcontractor 2</i>	
Date:	

ANNEX IX Document CHECKLIST

WHAT MUST BE INCLUDED IN THE TENDER SUBMISSION:

PLEASE TICK EACH BOX AND RETURN THIS CHECKLIST

TOGETHER WITH YOUR OFFER

- | | | |
|----|---|--------------------------|
| 1 | Technical Offer | <input type="checkbox"/> |
| 2 | Professional information (see Part 3 – Article 3.1) | <input type="checkbox"/> |
| 3 | Proof of financial and economic capacity (see Part 3 – Article 3.2) | <input type="checkbox"/> |
| 4 | Proof of technical and professional capacity (see Part 3 – Article 3.3) | <input type="checkbox"/> |
| 5 | Legal Entity Form ⁸ (Annex I) signed and dated | <input type="checkbox"/> |
| 6 | Financial Identification Form ⁹ (Annex II) signed and dated | <input type="checkbox"/> |
| 7 | Declaration on Honour on exclusion criteria (Annex III) signed and dated | <input type="checkbox"/> |
| 8 | Financial Offer (Annex IV) signed and dated | <input type="checkbox"/> |
| 9 | Administrative ID and Declaration form (Annex VI) signed and dated | <input type="checkbox"/> |
| 10 | Consortium form (Annex VII) signed and dated - if applicable | <input type="checkbox"/> |
| 11 | Sub-Contractors form (Annex VIII) signed and dated - if applicable | <input type="checkbox"/> |

****The tenderers' attention is drawn to the fact that any total or partial omission of documentation requested may lead the Contracting Authority to exclude the tender from the rest of the procedure.***

Print name:

Signature:

Date:

(of the Tenderer or authorised representative)

⁸ If you have provided a Legal Entity form to ENISA within the previous 12 months maximum and no details have changed in the meantime, then you may provide a photocopy of this previous form.

⁹ If you have provided a Financial Identification form to ENISA within the previous 12 months maximum and no details have changed in the meantime, then you may provide a photocopy of this previous form.