

**ANNEX I –Tender specifications
Open Procedure
Attached to the Invitation to tender**

**Invitation to tender N° EMSA /OP/03/2015 for
a Service Contract for the provision of a technical secretariat for the Group of Notified Bodies under
the Marine Equipment Directive and of an enhanced database for marine equipment approvals**

1. Introduction

The European Maritime Safety Agency (hereafter EMSA or Agency) was established under Regulation (EC) 1406/2002, as amended by Regulation (EU) 100/2013 of 15 January 2013, for the purpose of ensuring a high, uniform and effective level of maritime safety and prevention of pollution by ships.

The Agency's main objective is to provide technical, operational and scientific assistance to the European Commission and Member States in the proper development and implementation of EU legislation on maritime safety, pollution by ships and security on board ships. Against this background EMSA assist the Commission by preparing the updates to the technical Annexes of the Marine Equipment Directive "MED" (96/98/EC), maintaining the MarED database of EU approved marine equipment and preparing the implementation of the new Marine Equipment Directive (2014/90/EU). The Agency also provides assistance to the Commission in developing the technical annex of the Mutual Recognition Agreement with the USA.

- **Directive 96/98/EC, on marine equipment, as amended:**

The objective of the Directive 96/98/EC, as amended, on marine equipment is to enhance safety at sea and the prevention of marine pollution through the uniform application of the relevant international instruments relating to equipment to be placed on board ships. This Directive will be repealed as from 18 September 2016, by the Directive 2014/90/EU which has the same objectives as Directive 96/98/EC.

These Directives address equipment for which safety certificates are issued by or on behalf of Member States pursuant to international conventions. Thus the MED provides the legal basis to ensure the free movement of such equipment within the European Union, and on board European Union Member State flagged ships.

Ultimately, the Directive allows the manufacturers to gain access to the European Union market without multiple certification procedures and they are the principal beneficiaries of the MED.

- **Task of EMSA**

The European Commission has entrusted EMSA with several tasks concerning the technical management of the MED that are related to the scope of this Tender Specification:

- Product certification under the MED provisions is issued by the so called Notified Bodies. Notified Bodies are appointed by the European Union Member States Administrations as per Directive 96/98/EC Article 9 (and Directive 2014/90/EU Article 18). EMSA must perform the monitoring of the work of the Group of Notified Bodies which certify marine equipment on behalf of the Member States,

- The European Commission must keep an up-to-date list and database of approved equipment as per Directive 96/98/EC Article 10.4 and Directive 2014/90/EU Article 35.4. EMSA has been tasked with implementing the development and management of the database of EU approved marine equipment.

2. Objective, scope and description of the contract

The objectives of the contract are the following ones:

- Operation of a Technical Secretariat for the Group of Notified Bodies (MarED Group) performing product certification under the MED, as amended.
- Maintenance and update of the list of products subject to the MED.

The suitable management of these key tasks shall contribute to enhance the European Union Member States' cooperation and to a correct implementation of the MED. It will help to monitor the Notified Bodies' performance, to provide access to the information on commercial products under the MED. It shall also facilitate the exchange of information among the MED stakeholders for a wide range of particular subjects concerning international standardization, common interpretations and participation on further progress, and shall support the fight against counterfeit products.

2.1 Technical Secretariat for the Group of Notified Bodies (MarED)

European Union Member States may appoint Notified Bodies to act on their behalf for the purpose of certification of marine equipment listed in the MED, as amended.

Within the "New Approach Directives" framework, Notified Bodies are expected to exchange information in a view to a uniform application of the MED requirements and particularly in order to set up a harmonized implementation of the Conformance Assessment Procedures as defined in the MED.

According to the point 5.2.4. - "Coordination between notified bodies" - of the European Commission's "Blue Guide on the implementation of EU product rules 2014"; the European Commission, in coordination with European Union Member States, will ensure that the cooperation between the Notified Bodies is organized. As a result, the MED Notified Bodies form the Group of Notified Bodies for MED which is called the MarED Group (MarED).

The European Commission supported by EMSA is represented in the MarED Group. Governmental experts and representatives of the authorities directly responsible for the effective implementation of the directives can also participate as observers in the MarED Group.

In order to achieve a higher degree of efficiency in the Notified Bodies' work, the group can set up subgroups with a restricted number of participants to discuss specific technical questions. The MarED gathers its member's expertise within subgroups as per the categories of equipment contained in the MED, chiefly; lifesaving appliances, marine pollution prevention, fire protection, navigation equipment (including navigation lights) and radio-communication. Furthermore, the so called "Horizontal Committee" deals with the MarED management tasks and with issues related to the certification processes.

The MarED Group appoints its Chairman from among its members. A Technical Secretariat assists the MarED Group and its Chairman in its functions. Following the European Commission request, the Technical Secretariat services of the MarED Group is to be contracted by EMSA.

The tasks of the MarED Group's Technical Secretariat include the following:

- ASSISTANCE TO THE CHAIRMAN OF THE MARED GROUP OF NOTIFIED BODIES ACCORDING TO THE "NEW APPROACH DIRECTIVES".
 - The maintenance of the information flow between the secretariat and the Group of Notified Bodies with regards to the work of the inter-sectors Group of Notified Bodies when they meet.
 - The maintenance of the information flow between the secretariat and the Group of Notified Bodies with regards to the progress of the MED.
 - The maintenance of the information flow between the secretariat and the Group of Notified Bodies with regards to the development of international instruments and international and European standards.
 - The provision of technical advice to the chairman of the Group regarding the questions and issues that may be raised.

- MANAGEMENT OF THE MARED GROUP.
 - Update of the list of Notified Bodies following EMSA and European Commission directions.
 - Timely revision of the rules of procedure and terms of reference.
 - Documentary organization of the meetings of the MarED, the preparatory meetings of the expert groups and the meetings of the Horizontal Committee. This includes the preparation of agendas, attendance for the meetings, and drafting of the meetings' minutes.
 - Monitoring of the Notified Bodies' participation in the meetings and update of the members' contact list.
 - Monitoring of the Notified Bodies' participation in the follow-up of the certification files issued by their subsidiaries outside the European Union.
 - Participation, upon specific request of the Agency, in the meetings of the sub-groups of Notified Bodies when these sub-groups are set to deal with specific technical questions.
 - Participation in meetings organised by the Agency as well as in the meetings of the inter-sector groups of Notified Bodies.

- PUBLIC INFORMATION AND TECHNICAL OUTCOMES MANAGEMENT
 - The Technical Secretariat shall regularly update the list of Notified Bodies as per their fields of expertise following European Union Member States' initial appointment. It shall also make publicly available the follow-up of their notification with regard to the dates of audit of their technical performance by the appointing Administration or by any other third party.
 - The Technical Secretariat shall ascertain that Notified Bodies forming the MarED Group are listed in the NANDO list. NANDO is the Information System of the European Commission for the New Approach Notified and Designated Organisations. Notification is an act whereby a Member State informs the Commission and the other Member States that a

body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive. Notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State.

- Concerning the list of certified products, the Technical Secretariat shall ensure the daily management and the integrity of the list of marine equipment which are certified by Notified Bodies. This list shall be made publicly available only when all the required modules (B+D, B+E, B+F, G, etc.) have been certified for a product model. Products holding only module B certification shall also be listed by the Technical Secretariat but the access to those “only module B” details shall be restricted to EMSA for the purpose of assisting the European Union Member States’ control.
 - The MarED Technical Secretariat shall invite both Notified Bodies and economic operators to provide a copy of the declarations of conformity, with explicit reference to their certificates and thus to make publicly available the list of approved equipment as per MED.
 - The Technical Secretariat shall draft technical working documents, technical meeting reports and technical recommendations drawn up for the Group of Notified Bodies known as the Approved Draft Recommendations (ADR). The Technical Secretariat shall make available a current list of ADR under discussion in order to make easier for any other MED stakeholders to discuss their comments for further consideration. The Technical Secretariat shall set up a public e-mail inbox for suggestions on ADR from stakeholders other than Notified Bodies or Administrations.
 - With regard to the agreement of the MarED group, the MarED Technical Secretariat shall define with EMSA a detailed procedure on ADR drafting and follow-up, following ADR endorsement. It shall keep a list of approved recommendations with explicit reference to MED item number and all the cross references to standards and other approved recommendations, with a view to preventing inconsistent information. The Technical Secretariat shall make publicly available the list of Approved Recommendations on the MarED Web Site.
 - Questions and answers management: the MarED Technical Secretariat shall manage the incoming, record and control of all the questions and answers brought to the MarED Group’s attention by MED stakeholders.
 - The MarED Technical Secretariat shall hold the initiative to propose the publication of technical issues of general interest on the MarED Web Site. Publication shall be effective following EMSA consideration and European Commission authorization.
- MANAGEMENT OF MED STAKEHOLDERS INTERACTIONS, INTERESTS AND CONCERNS.
 - The MarED Technical Secretariat shall promptly report to EMSA any disputes concerning certification issues, failure of mutual recognition of certificates among Notified Bodies, complaints to Notified Bodies, etc., regardless of the instigator of the point.
 - The MarED Technical Secretariat shall promptly report to EMSA any issue of counterfeit or fake equipment that may reach the MarED Technical Secretariat, regardless of the source of the information.
 - The MarED Technical Secretariat shall gather the contributions of Notified Bodies for the update of MED annex A and shall timely report them to EMSA.
 - The MarED Technical Secretariat shall participate in the meetings organised by Administrative Institutions upon EMSA’s request (i.e. stakeholder consultation on Marine Equipment).

- The MarED Technical Secretariat will be able to present to EMSA proposals for the organization of dedicated workshops on MED issues, in particular, to enhance a better knowledge of roles among stakeholders and to improve the communication with the Maritime Sector. Following EMSA's and COM's approval, the MarED Technical Secretariat shall be authorized to organize the events under regular commercial conditions.
- COMMITMENT FOR THE SUSTAINED PERFORMANCE IMPROVEMENT OF THE MARED GROUP OF NB.
 - The MarED Technical Secretariat shall yearly survey Notified Bodies on the difficulties found for exercising their activities and shall report to EMSA accordingly.
 - The MarED Technical Secretariat shall implement a system to control the performance of the MarED Group, to EMSA's satisfaction.

2.2 Maintain and update a list of marine equipment products under MED

According to the MED Article 10.4 and to the new MED Article 35.4, the European Commission has the obligation to keep “an up-to-date list of approved equipment and applications withdrawn or refused and shall make it available to interested parties”. This legal obligation shall be implemented through the MarED Product Database.

The MarED Product Database shall be made of a number of tables which shall contain the relevant data sets for product certification and approval of marine equipment. Currently EMSA is the only owner of these tables and their datasets. Under the contract stemming from this call for tenders, EMSA shall be the only owner of these tables and their datasets, without any exception, at any time. The contractor shall maintain the integrity of all those datasets from the moment they are provided by the Notified Bodies to the contractor for their inclusion into the MarED Product Database.

In addition, the contractor shall have the obligation to issue all the forms intended to populate the tables and also all the queries oriented to set up reports. The issuance of such information will be done by the contractor in paper hardcopy and on electronic files which shall make it easier for EMSA to import datasets to Oracle 11g. The information shall, at least, contain all DDL statements for creation of database objects, descriptions of the tables and fields as well as the Entity Relationship Diagram (ERD) describing the relationship between tables. All the information mentioned above concerning datasets into their tables, forms to tables, and queries to reports shall be backed up and copied by the contractor for delivering to EMSA every 2nd and 7th month of every 12 month period of the current yearly service contract. EMSA shall keep that back-up for security storage purpose.

Below in this document are outlined the following aspects of the project:

- The Requirements Baseline (RB) of EMSA for the database of certified marine equipment.
- The minimum contents of the expected draft Technical Specification (TS) to be provided by the tenderers.

Tenderers are expected to deliver a tender containing a draft TS based on EMSA's RB.

The contractor shall be responsible for managing and keeping up to date the existing database on authorised products under the MED. The tasks shall include 100% coverage of the authorised products in the database and closer coordination with the Notified Bodies to regularly submit their respective data. The contractor shall also establish and practise sustainable and continuous procedures with the Notified Bodies to update their datasets at least on a monthly basis.

The database shall have the ability to query the content of the certificates. The query tools shall allow the extraction of information necessary to monitor the implementation of the MED with regard to:

- The scope of the notification of Notified Bodies issued by the European Union Member States, as per MED provisions.
- The modules of conformity assessment applied for the products certification.
- The volume of certification, particularly the number of units of a given marine equipment item available in the market, details on their limitations of use related to safety and the particular features of the products.
- The availability of reliable information concerning the safety investigations as per Article 13 of Directive 96/98/EC and Chapter 5 of Directive 2014/90/EU.
- The approval of innovative equipment by EU Member States as per Article 14 of Directive 96/98/EC and Article 30 of Directive 2014/90/EU and the information dissemination among other EU Member States.

2.2.1. Requirements baseline of the MarED Product Database

The requirements baseline and the current features of the MarED Product Database are as follows:

- Input.
- Fields of the database.
- Data import.
- Database queries.
- Database evaluation.
- MarED IntraNet User Management.
- MarED website (public, registration required).
- Time availability in minutes: 95 % of 24 hours/day over 7 days/week.

The MarED Product database shall be continuously implemented into a website with regard to the following essential features:

Input:

- The existing database includes about 90.000 datasets of product entries. For migration purposes from the current hosting to another server, the existing database will be made available in the form of tables containing a primary key connected to a foreign key in another table. Data retrieving shall be available by SQL statements which shall make it easier to look at the data tables and to select data there from. Two categories of SQL statements can be declared, namely, DDL statements (to build and modify the structure of the tables and other objects in the database) and DML statements (to work with the data in tables).

Fields of the database:

- Product: (ITEM NUMBER, RELATED DIRECTIVE, PRODUCT NAME, TRADE NAME, RESTRICTION OF USE).
- Applicant: (SHORT NAME, LONG NAME, STREET, ZIPCODE, CITY, POBOX, COUNTRY, PHONENUMBER, FAXNUMBER, EMAIL, URL).
- Manufacturer: (SHORT NAME, LONG NAME, STREET, ZIPCODE, CITY, POBOX, COUNTRY, PHONENUMBER, FAXNUMBER, EMAIL, URL).
- Notified Body (NOTIFIED BODY NUMBER).
- Certificate (CERTIFICATE NUMBER, DATE OF CERTIFICATE ISSUE, DATE OF CERTIFICATE VALIDITY, COMMENT TO CERTIFICATE, NOTIFIED BODY NUMBER).
- Module (APPLIED MODULE).
- Authorization (AUTHORIZATION NUMBER, COMMENT TO AUTHORIZATION, DATE OF AUTHORIZATION).

- Withdrawal (DATE OF WITHDRAWAL, COMMENT TO WITHDRAWAL).
- Refusal (DATE OF REFUSAL, COMMENT TO REFUSAL).
- USCG (USCG APPROVAL NUMBER, COMMENT TO USCG).
- Data Base for the Declarations of Conformity (DoC) as signed by the relevant stakeholder (manufacturer, applicant, importer, installer, etc, who will provide the DoC to its NB-certifying the follow up of the production-, and then that NB will forward the DoC to the MarED DB Administrator).

For every DoC, the following fields shall be shown:

- Product: (ITEM NUMBER, ONLY ONE PRODUCT NAME and ONLY ONE MODEL, TRADE NAME).
- Signature of the economic operator (One of the following: manufacturer, authorized representative, applicant, importer distributor or installer, etc).
- Related NB Certificates as stated into the DoC:
 - either:
 - EC Type Examination Certificate Number (MODULE B),
 - Follow up of production Certificate (MODULE D, E or F),
 - or:
 - Unit verification certificate (MODULE G).
- Hyperlink to the DoC in .pdf format, where the .pdf have been provided to the database administrator.

Data import:

- Around 40 Notified Bodies report updates of their databases every 1-3 months.
- Notified Bodies' Databases are delivered in XLS or XML format. Notified Bodies are not necessarily using the same format for their databases.
- Import of XLS and XML files into the MarED database to be performed within 10 working days after delivery of input data.
- Input evaluation. Notified Bodies' data have to be checked during the import procedure with regard to completeness of datasets (as per the defined fields of the database), format conventions and logical correctness which must allow database entities to successfully interact which each other for cross analysis purposes). Errors have to be reported back to Notified Bodies and corrections shall be requested. Data inserted in the database shall be normalised and have suitable relational constraints (index, primary and foreign keys) applied.

Database queries:

A web interface with two levels of search functions has to be supplied for providing:

- Simple (keyword) search in all fields.
- Advanced search (Product or trade name, Applicant, Manufacturer, Notified body, Certificate number, Status of certificate, Commission directive, Item number (A.X/X.X), USCG number (XXX.XXX), Type of approval).
- Distinction between products in the database where the validity of certificates is expired (but which can still be found on built ships) and those for which certificates are actually still valid (available on the market).

Database evaluation:

- Display of Notified Bodies' Databases portfolios triggered online (evaluation of authorisations per item and module).
- Display of overall Notified Bodies' Databases portfolios triggered (suitable graphical representations of authorisations per item, per module, per category, which will be intended to visually compare certification activity).

MarED IntraNet User Management:

- The access to MarED intranet (including website, internal information management and MarED product database) requires registration and hierarchical access and user rights management (read, write, edit, etc.) which shall be granted by the MarED Technical Secretariat.
- The current application manages about 18.000 registered persons from about 100 countries. About 150 persons are registered from Notified Bodies and Member States with hierarchical access to 9 internal working groups. New working ad-hoc groups may be set up according to matters of interest arising.
- Each working group has its own working suite with functions for member management, event management, document management and message/discussion board. The MarED intranet hosts about 2.400 documents. Version management of documents is required.
- Access and usage of the MarED intranet, especially by registered visitors shall be statistically evaluated. Consequently it is necessary to track “who consults what”, in order to analyse the quality of the information supplied. This includes monitoring of intranet access and access to the MarED product database; visitors shall be categorized in a suitable way (e.g. surveyor, manufacturer, administration).

MarED website (public registration required):

- Handling 400 registered users a day.
- Mapping and continuous updating of the list of Notified Bodies.
- Downloadable versions of the MED and the Mutual Recognition Agreements.
- Listings of items subjected to MED, as amended (taking into account the current 10 amendments of Annex A as per the relevant Commission Directives), including information about applicable rules and regulations. Integrated access to MarED product database search engine and statistical evaluation of the item (internal use only).
- Tool for dynamic updating of applicable rules, regulations and technical standards related to individual items of the most recent directive. Updating by Technical Secretariat following advice of the MarED’ expert sub-groups. (Internal or public use to be decided by European Commission assisted by EMSA).
- Functions to display public news or press releases.
- Public listing of MarED Approved Recommendations including links to items concerned, respectively to the relevant articles or attachments of the directive.

Time availability: Availability shall be expressed in minutes and will be ensured at, at least, 95 % of 24 hours/day over 7 days/week. A quarterly report will be provided within the next 7 days after the end of each respective quarter of the calendar year.

Data set availability: The dataset shall be available in tabular format in order to facilitate their quick integration into any other tabular platform. Data retrieving shall be available by SQL statements, thus facilitating to look at of the tables and selecting data therefrom. Two categories of SQL statements are available, namely, DDL statements (to build and modify the structure of your tables and other objects in the database) and DML statements (to work with the data in tables). A back-up of datasets shall be delivered to EMSA every 2nd and 7th month of every 12 month period of the current yearly service contract.

2.2.2. Technical Specification of the MarED Product Database - Minimum contents

The tenderer shall provide a draft “Technical Specification” intended to fulfil the database’s “Requirements Baseline” given in the point 2.2.1 of this Tender Specification.

The draft Technical Specification shall outline the following 12 major points of interest with regard to the given “Requirements Baseline” (Refer to point 2.2.1 of this document):

1. **Purpose:** Define the purpose of the database. Be specific about how the database will perform and how this will support the work of EMSA.
2. **Data items:** Make a list of the major entities about which information will be captured (documents for dedicated certification, users, MarED documents, etc). For each of these, list the specific information which will be needed.
3. **Entity relationships:** For each of the aforementioned “Data items”, describe how it relates to other entities.
4. **Functionality:** Document how the data will be used and what specific operations the database will perform; namely, define at least the facilities: to automate mail-outs for MarED Group notifications, to generate reports, to facilitate searching and matching, to perform statistical analysis, to enquire MED stakeholders on ADR under discussion and to document the delivery status to EU MS Administrations of ADR under discussion.
5. **Data quality.** Describe how this data will be captured from Notified Bodies and (where appropriate) kept up to date. Identify who will be responsible in your organisational chart for updating datasets. Identify what is at stake in the accuracy of the data. Identify how important data quality is to the operation EMSA business. Identify what are the potential risks and costs associated with incomplete or inaccurate data.
6. **Business rules:** Define any business rules which apply to the data. For example, a) define what determines whether a certificate (or any other entity of the database is considered “active”; b) define the mandatory pieces of entity information (such as product designation, factory address, applicable rules of certification); c) define who has the authority to authorise any particular dataset update (this definition will result in the update of the existing rules of procedure of the MarED Group).
7. **Classifications:** Document any classification schemes which might be used by the database, so that the data, which is categorised in a systematic and meaningful way, will be much easier to search, sort and report on. Explain how the chosen classification schemes make the data manageable.
8. **User interface:** Describe how the user interface will look and interact. Describe how the user might navigate between different parts of the application, as well as specific functionalities such as searching, adding new records, updating existing records, etc.
9. **Reports:** Describe the reports which will be available. This should include listing the specific information to be contained in each report, as well as details of any calculations, sorting, grouping or filters which need to be applied to the data. It can be particularly helpful to have an example of how each report will look.
10. **Security:** Explain how access to the data will be restricted for those products holding only MED Module B certificates. Identify the sensitive information contained in the database concerning the date of validity of certificates, the overlapping of validity date for Module B on its related production follow-up certificates and the early identification of production follow-up certificates based on expired Module B certificates. Identify which information will be accessible to people outside your organisation (eg. via the Internet). Identify whether the sensitive information will need to be accessible to staff who aren’t connected to your local or wide area network. Identify who will be able to read, add, edit or delete data. Explain

whether your organisation has security standards or protocols which would apply to this application.

11. **Scale:** Explain which relational database management software you propose, taking into account an optimal match between costs (both in acquiring, setup and maintenance) commensurate with the expected size of the database after four years of activity, and the amount of work it may be required to do. Provide your estimation about how many records the database is likely to contain after four years. Outline a plan on how often data is expected to be added, changed or deleted. Explain how the database will handle 400 users per day. Confirm whether the database will be available 95% of 24 hours a day, 7 days a week. Explain the measures taken to prevent corruption of data and for the timely recovery of systems and/or data. Describe the systems and software used for providing web access to the MarED data.
12. **Operating environment:** Describe your organisation's current hardware and software environment. Important considerations include the kind of network which is in place, the relevant hardware specifications, operating systems and business software in general use, and any standards and/or plans for the future your organisation has in relation to these.

3. Contract management responsible body.

The European Maritime Safety Agency – Unit B.2, in charge of Ship Safety – will be responsible for managing the contract.

4. Project Planning

The Contractor shall submit the following reports within a 12 month contractual period:

4.1 For the MarED Technical Secretariat with regard to certification matters, declarations of conformity, Notified Bodies outcomes (ADR, AR and planned ADR), catalogue of AR in force and MED stakeholders' list of questions and answers:

- Two management activity follow-up reports (after month 5 and 10).
- One final activity draft report (summary of MARs after month 11).
- One final activity report (after month 12).
- Two draft minutes – MarED Group meetings.

3 copies of the reports shall be supplied in paper form and one copy in electronic form.

4.2 For the MarED on-line list of certified equipment and declarations of conformity:

- Four quarterly reports on data base availability;
- List of Declarations of Conformity as available on line as referred to their certificates.

The reports on data base availability shall be supplied by e-mail no later than 7 January, 7 April, 7 August, and 7 October of the corresponding contract year.

A back-up of datasets shall be delivered to EMSA every 2nd and 7th month of every 12 month period of the current yearly service contract.

4.2. Foreseen meetings

For every 12 month period of service, the contractor is expected to hold 5 meetings within a 12 month contractual period:

- One kick-off meeting to report about the technical secretariat management and points of general interest for the yearly exercise, (during month 1, venue in EMSA premises in Lisbon, Portugal),
- Two preparatory meetings with the MarED Chairman for the meeting of the Notified Bodies MarED Group (after month 1 and 5, venue to be determined by agreement with the Chairman).
- Two meetings of the Notified Bodies MarEd Group (after month 2 and 7 in Lisbon, Portugal).

The cost of these meetings for every 12 month period of service shall be included into the price offered by tendered bids as EMSA will not reimburse any additional expense to the awarded contractor.

4.3 Estimate of the amount of work involved

The whole amount of work involved to carry out this service contract is estimated at 95 person-days per year of contract.

5. Timetable

The estimated date for signature of the contract is October - November 2015.

The timetable for the delivery of reports and timetable of meetings have been stated above with regard to a period of 12 months. Refer to point 4.2.

6. Estimated Value of the Contract

The estimated budget available for this contract is of **380,000** Euro excluding VAT for a maximum period of 48 months.

7. Terms of payment

Payments shall be issued in accordance with the provisions of the **draft service contract** available on the Procurement Section under the call to tender EMSA/OP/03/2015 on the EMSA website at the following address: www.emsa.europa.eu

8. Terms of contract

In drawing up a bid, the tenderer should bear in mind the terms of the draft service contract. EMSA may, before the contract is signed, either abandon the procurement or cancel the award procedure without the tenderers being entitled to claim any compensation.

9. Financial guarantees

Not applicable.

10. Sub-contracting

If the tenderer intends to either sub contract part of the work or realise the work in co-operation with other partners he shall indicate in his offer which part will be subcontracted, as well as the name and qualifications of the subcontractor or partner. (NB: overall responsibility for the work remains with the tenderer).

The tenderer must provide required evidence for the exclusion and selection criteria on its own behalf and when applicable on behalf of its subcontractors. The evidence for the selection criteria on behalf of subcontractors must be provided where the tenderer relies on the capacities of subcontractors to fulfil selection criteria¹. The exclusion criteria will be assessed in relation to each economic operator individually. Concerning the selection criteria, the evidence provided will be checked to ensure that the tenderer and its subcontractors as a whole fulfil the criteria.

11. Requirements as to the tender

Bids can be submitted in any of the official languages of the EU. The working language of the Agency is English. Bids must include an English version of the documents requested under point 14.5 & 15.1 of the present tender specifications.

The tenderer shall complete Tenderer's checklist.

If the tenderer intends to either sub contract part of the work or realise the work in co-operation with other partners (Joint Offers) he shall indicate in his offer by completion of the form – Information regarding joint offers and subcontracting.

The tender must be presented as follows and must include:

Signed cover letter indicating the name and position of the person authorised to sign the contract and the bank account on which payments are to be made.

Financial Form completed, signed and stamped; available on the Procurement Section (Financial Form) on the EMSA Website at the following address: www.emsa.europa.eu

Legal Entity Form completed, signed and stamped and requested accompanying documentation, available on the Procurement Section (Legal Entity Form) on the EMSA Website at the following address: www.emsa.europa.eu

Tenderers are exempt from submitting the Legal Entity Form and Financial Form requested if such a form has already been completed and sent either to EMSA or any EU Institution previously. In this case the tenderer should simply indicate on the cover letter the bank account number to be used for any payment in case of award.

Part A: all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the points **13, 14.2-14.3** of these specifications (part of the Exclusion criteria)

¹ To rely on the capacities of a subcontractor means that the subcontractor will perform the works or services for which these capacities are required.

Part B: all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the **Economic and Financial capacity** (part of the Selection criteria) set out under point **14.4** of these specifications;

Part C: all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the **Technical and professional capacity** (part of the Selection Criteria) set out under point **14.5** of these specifications.

Part D: all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the **Award Criteria** set out under point **15.1** of these specifications;

Part E: setting out **prices** in accordance with **point 12** of these specifications.

12. Price

Price for a Service Contract within a 12 month period shall include the provision of services:

- for operating a Technical Secretariat for the Group of Notified Bodies (MarED) performing product certification under the MED, as amended (MED) and;
- for maintaining and updating a list of products under the MED.

The price (for every 12 month period of service) shall include all contractor's expenses for five foreseen meetings, as EMSA will not reimburse any additional expense (travel tickets, daily allowance, accommodation expense, etc.) to the awarded contractor.

Prices must be quoted in Euro.

Prices must be fixed amounts, non-revisable and remain valid for the duration of the contract. Estimated travel and daily subsistence allowance expenses must be indicated separately.

Under Article 3 and 4 of the Protocol on the privileges and immunities of the European Union, EMSA is exempt from all duties, taxes and other charges, including VAT. This applies to EMSA pursuant to the Regulation 1406/2002/EC. These duties, taxes and other charges can therefore not enter into the calculation included in the bid. The amount of VAT must be shown separately.

13. Joint Offer

Groupings, irrespective of their legal form, may submit bids. Tenderers may, after forming a grouping, submit a joint bid on condition that it complies with the rules of competition. Such groupings (or consortia) must specify the company or person heading the project and must also submit a copy of the document authorising this company or person to submit a bid.

Each member of the consortium must provide the required evidence for the exclusion and selection criteria. The exclusion criteria will be assessed in relation to each economic operator individually. Concerning the selection criteria the evidence provided by each member of the consortium will be checked to ensure that the consortium as a whole fulfils the criteria.

If awarded, the contract will be signed by the person authorised by all members of the consortium. Tenders from consortiums of firms or groups of service providers, contractors or suppliers must specify the role, qualifications and experience of each member or group.

14. Information concerning the personal situation of the service provider and information and formalities necessary for the evaluation of the minimum economic, financial and technical capacity required

14.1 Legal position – means of proof required

When submitting their bid, tenderers are requested to complete and enclose the **Legal Entity Form** and requested accompanying documentation, available on the Procurement Section (Legal Entity Form) on the EMSA Website at the following address: www.emsa.europa.eu

14.2 Grounds for exclusion - Exclusion criteria

To be eligible for participating in this contract award procedure, tenderers must not be in any of the following exclusion grounds:

- 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 are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) they have been convicted of an offence concerning their professional conduct by a judgement which has the force of res judicata;
- c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- d) 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;
- e) 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 Union financial interests;
- f) they have been the subject of the administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the procurement procedure or failing to supply an information, or being declared to be in serious breach of his obligation under contract covered by the budget.

14.3 Evidence to be provided by the tenderers

For this purpose the Declaration on Honour available on the Procurement Section on the EMSA Website (www.emsa.europa.eu) shall be completed and signed.

Please note that the tenderer to whom the contract is to be awarded shall provide additional proof evidencing eligibility.

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.

When the tenderer to be awarded the contract has already submitted relevant evidence to EMSA, it remains valid for 1 year from its date of submission. In such a case, the reference of the relevant project(s) should be mentioned and the Contractor is required to submit a statement of confirmation that their situation has not changed.⁴

14.4 Economic and financial capacity – Selection criteria

Requirements:

- The tenderer must be in stable financial position and the economic and financial capacity to perform the contract

Evidence:

- Financial statements for the last three years for which accounts have been closed.
- Statement of overall turnover and turnover relating to the relevant services for the last three financial years.
- Tenderers are exempt from submitting the documentary evidence if such evidence has already been completed and sent to EMSA for the purpose of another procurement procedure and still complies with the requirements. In this case the tenderer should simply indicate on the cover letter the procurement procedure where the evidence has been provided.

- If, for some exceptional reason which EMSA considers justified, a tenderer is unable to provide one or other of the above documents, he may prove his economic and financial capacity by any other document which EMSA considers appropriate. In any case, EMSA must at least be notified of the exceptional reason and its justification in the tender. EMSA reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

14.5 Technical and professional capacity – Selection criteria

EMSA must perform the selection of the potential contractor based on its technical professional capacity. Thus, the tenderer shall include in its tender the information required below, and the necessary documentary evidence for the following aspects:

Technical Competence

- The details of educational and professional qualifications of the persons providing the services (detailed CV's have to be included) proving a relevant in-depth knowledge of this subject matter of this tender.

Tenderers should provide their bids with a detailed curriculum vitae of each member of the team responsible for carrying out the work, including his or her educational background, degrees and diplomas, professional experience, research work, publications and linguistic skills. The curricula vitae shall be presented, preferably, in accordance to the Commission Recommendation on a common European format for curricula vitae, published in OJ L79 of 22 March 2002, p. 66.

- A list of the principal related projects in the past 5 years proving previous merits and experience in the field covered by the MED certification. Evidence of knowledge and experience in the fields mentioned above shall be provided on the basis of a list of related services in which the tenderer has participated and worked. This shall include a description of the services with indication of respective objectives, contracting parties, duration and budget.
- The tenderer shall provide evidence of his proven knowledge of international instruments as well as of international, European and USA testing standards for marine equipment within the full scope of the MED and the EU-USA MRA. Furthermore, the tenderer must be able to demonstrate his experience in the assessment of relevant legislation and standards in this field.
- The tenderer shall provide evidence of his proven knowledge of the field related to the certification of Marine Equipment products.
- The tenderer shall provide evidence of its proven knowledge to manage list of approved equipment under New Approach Directives.

For selection purpose, tenderers shall provide the required information concerning the five aspects above.

Independence

A statement of independence and absence of conflicts of interest in relation to MED stakeholders (EU MS, Notified Bodies and manufacturers of marine equipment under MED) must be included in the offer.

15. Award criteria

Only the tenders meeting the requirements of the exclusion and selection criteria will be evaluated in terms of quality and price.

15.1 The contract will be awarded to the tenderer who submits the most economically advantageous bid (the one with highest score) based on the following quality criteria and their associated weightings (please, refer to section 15.2):

1. Quality criterion 1, Q_1 , ($W_1 = 10\%$): Proposed methodology and the overall approach to the project management
2. Quality criterion 2, Q_2 , ($W_2 = 40\%$): Proposed methodology for operating a technical secretariat for the notified bodies operating product certification under MED.
3. Quality criterion 3, Q_3 , ($W_3 = 20\%$): Proposed methodology for the management, update and maintenance of the list for product certificates, and database users based on the existing database at www.mared.org.

and the price criterion and associated weighting:

4. Price of the bid ($W_{Price} = 30\%$).

For all bids evaluators will give marks between 0-10 (half points are possible) for each quality criterion.

The score is calculated as

$$S = SQ + SP$$

where:

The average quality for quality criterion i is

$$Q_i = \frac{1}{\text{number of evaluators}} * \sum_{\text{evaluator}} \text{mark of the evaluator for quality criterion } i$$

The overall weighted quality is

$$Q = \sum_i Q_i * W_i$$

The score for quality is

$$SQ = \frac{Q}{Q \text{ of the bid with highest } Q} * 100 * \sum_i W_i$$

The score for price is

$$SP = \sum_i \frac{\text{lowest Price}_i \text{ of all bids}}{\text{Price}_i} * 100 * W_{Price_i}$$

Only bids that have reached

- a minimum of 60 % for Q_1 ,
- a minimum of 60 % for Q_2 ,
- a minimum of 60 % for Q_3 ,

will be taken into consideration when calculating the score for quality SQ , score for price SP and score S .

Only bids that have reached a minimum of 70 % for the score S will be taken into consideration for awarding the contract.

15.2 Detailed technical aspects. The following technical aspects will be assessed for the purpose of quality criterion assessment:

- **Quality criterion 1 (10 %).** Proposed methodology and the overall approach to the project management. This must include detailed proposals of how the project as a whole would be carried out. The proposed methodology shall outline, at least, the following aspects:
 1. A 12-months term action plan, including key milestones, meetings, reporting, and invoice delivery.
 2. Description of the proposed strategy for management of the MarED Group with regard to the New Approach Directives doctrine.
 3. Description of the proposed methodology for management of ADR production including a proposed plan for timely delivery of MarED ADR proposals to COSS.
 4. Description of a methodology for replying to MED Stakeholders questions, expected communication channel for managing prior approval from EU institutions on draft replies and expected reaction time.
 5. Presentation showing the tenderer's understanding of the role of Notified Bodies and implications of the list of approved equipment under MED.
- **Quality criterion 2 (40 %).** Proposed methodology for operating a technical secretariat for the notified bodies operating product certification under MED. The proposed methodology shall show how the contractor will manage international groups of interest with regard to MED issues. Thus the proposed methodology shall be complemented by appending answers to the following generic issues as currently submitted by MED stakeholders asking for advice and guidance:
 1. The Directive 2014/90/EU will repeal the Directive 96/98/EC in September 2016. The new legislative text has been drafted with a view to simplify the original MED, For implementing that legislation simplification the so called new legislative approach pack was incorporated and tailored to the marine equipment sector. Please identify and outline a general idea about the two main legal acts for the referred new legislative approach pack.
 2. EU MS Administrations may appoint third party organizations to act on their behalf for the purpose of product certification as per MED provisions. Those organisations are the so-called Notified Bodies. Please, describe two different options as to how EU MS administrations may manage to ensure that their Notified Bodies meet the criteria of MED Annex C.
 3. Reference is made to any certificate concerning MED item number A.1/3.12. Regarding the contents of that certificate for module B as issued by a Notified Bodies, please, explain the meaning of "limitation of use", list two parameters limiting the use of pressure/vacuum valve, explain its importance for engineering a complex system and explain where those parameters limiting the use of valves are stemming from.
 4. Explain the difference and relation between a MED certificate and a declaration of conformity under MED.
 5. Explain when a product under MED can be deemed to be lawfully put into the market of the EU.

6. Concerning the technical documents produced by a Notified Body explain what an “Approved Draft Recommendation” is and how it may reach the status of Approved Recommendation.
 7. Explain how the list of products under MED is currently made available to interested parties and what is its original legal basis.
 8. The current MarED web site is www.mared.org . Access to its information is public and granted following free registration. Find the order of magnitude concerning the number of certificates issued under the 4th Amendment of MED annex A.
 9. Should a Notified Body have to subcontract a test laboratory, please advise on some standard to have under control the testing service quality of the concerned subcontractor.
 10. Which two elements should accompany a testing measurement in all cases?
 11. Explain the contents of a technical file supporting a certificate for MED.
 12. Who performs the follow-up of a product production and which are the options for documenting the follow-up as a positive outcome under MED?
 13. What is the essential reference document for initiating the follow up of a production with a view to getting the production certification under module D? Explain the importance and role of that reference document and how its validity period may affect the follow-up of the involved production.
 14. Describe under which circumstance the MarED Group may need the Committee of Safe Seas and Pollution Prevention from Ships (COSS) to endorse the documents drafted by the MarED Group.
 15. What is the role of a Notified Body in relation to MED Market Surveillance?
 16. What is the role of a Notified Body when an EU MS Administration invokes MED Safeguard Clause?
 17. What is the role of EU MS Administrations within the MarED Group?
 18. Explain the relationship between the USA Administration and the EU with regard to marine equipment.
 19. What is the status of a Notified Body under MED in relation to the USA Administration concerning product certification?
 20. Describe the standard elements of New Approach Directives and describe which particular shape replaces the CE Mark in the MED.
- **Quality criterion 3 (20 %).** Proposed methodology for the management, update and maintenance of the list for product certificates, and database users based on the existing database at www.mared.org. The proposed methodology shall outline, at least, the following aspects:
 1. A draft “Technical Specification” shall be provided. The tenderer shall provide a draft Technical Specification with regard to the provisions of point 2.2.2. This draft Technical Specification shall be done in terms of the Requirements Baseline of EMSA as per point 2.2.1.
 2. The tenderer shall provide evidence of its proven expertise on developing producing and maintaining databases.
 3. The tenderer shall provide evidence of its proven expertise to safely move the existing datasets to the relevant server and to set up the users’ suites in full operation within 8 weeks. The tenderer shall provide evidence of proven expertise to manage the importation of datasets to its proposed platform.
 4. The tenderer shall provide evidence of proven expertise to manage the exportation of datasets to a third platform.
 5. The tenderer shall provide evidence of its proven expertise to manage the availability of the relevant software licences.

16. Contracts will not be awarded to 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.

17. False declarations

Without prejudice to the application of penalties laid down in the contract, tenderers and contractors who have been guilty of making false declarations concerning situations referred to in points 14 and 15 above or have been found to have seriously failed to meet their contractual obligations in an earlier procurement or grant shall be subject to administrative and financial penalties set out in Article 145 of Commission Delegated Regulation of 29.10.2012 on the rules of application of Regulation (EU) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.

18. Intellectual Property Right (IPR)

Please consult the contract for IPR related clauses.

If the results are not fully created for the purpose of the contract this should be clearly pointed out by the tenderer in the tender. Information should be provided about the scope of pre-existing rights, their source and when and how the rights to these rights have been or will be acquired.

In the tender all quotations or information originating from other sources and to which third parties may claim rights have to be clearly marked (source publication including date and place, creator, number, full title etc.) in a way allowing easy identification.