European Maritime Safety Agency

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

Invitation to tender N° EMSA /OP/04/2015 for
A contract concerning
a Study on the yearly updating of the regulatory provisions for the certification of the marine equipment subject to the Marine Equipment Directive, as amended (Council Directive 96/98/EC and, as of 18 September 2016, Directive 2014/90/EU) and of the marine equipment as listed in Annex II of the EU-USA Mutual Recognition Agreement (Council Decision 2004/425/EC).

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 (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.

Council Directive 96/98/EC, as amended, on marine equipment (MED) seeks 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 for which safety certificates are issued by or on behalf of Member States pursuant to international conventions and to ensure the free movement of such equipment within the Community.

The Directive 2014/90/EU will repeal the Directive 96/98/EC, as amended, as of 18 September 2016. The new directive introduces a simpler system for the transposition of EU legislation, strengthens the requirements for the notification and control of conformity assessment bodies and enhances market surveillance. It also mandates the Commission to carry out a cost-benefit analysis concerning the use of electronic tagging in order to prevent counterfeiting and for market surveillance purposes.

The new Directive also includes new elements into the database, notably information concerning the manufacturer’s Declarations of Conformity.

Additionally the European Commission also identified the need for providing the MED stakeholders with certain relevant dates for the implementation of their different obligations. Such a new element of consideration refers to the specific dates governing the implementation of the technical reference standards for the certification of equipment.

Within the context of the Trans-Atlantic Economic Partnership (TEP) Action Plan, the European Union (EU) and the United States of America (USA) negotiated a Mutual Recognition Agreement (MRA) on marine equipment that came into force on July 1st 2004. The objective is to base the MRA on the

equivalence between the respective EU and US technical requirements and conformity assessment procedures for marine equipment. This is facilitated by the fact that both the EU and USA have, to a very large extent, based their requirements on the existing international instruments of the International Maritime Organization (IMO).

The EU-USA MRA for marine equipment stems from the MED. The marine equipment items included in the EU-USA MRA were deemed as equivalent with regard to the provisions intended for their certification.

A MRA based on equivalence would mean that marine equipment complying with EU legislation and standards and having undergone prescribed conformity assessment procedures will be accepted by the USA as fulfilling their requirements and vice-versa. Such an agreement offers considerable trade facilitation.

For the purpose of the MED the marine equipment is listed in Annex A. For the purpose of the EU-USA MRA the marine equipment is listed in Annex II. The update of MED Annex A is linked to the update of EU-USA MRA and the update of the latter will match the former, as far as the equivalence of their regulatory provisions can be ascertained.

2. Objective, scope and description of the contract

The purpose of the contract is to obtain a study intended to update the regulatory provisions for the certification of marine equipment as listed at:

- Annex A of the Marine Equipment Directive or into the new implementing act foreseen by Article 35 of Directive 2014/90/EU, as amended.
- Annex II of the EU-USA Mutual Recognition Agreement for marine equipment.

The study shall provide the list of the regulatory provisions in their up-to-date version for the certification of marine equipment. For the purpose of this contract, “regulatory provisions” for the certification of marine equipment are:

- International instruments. International instruments shall mean the relevant international conventions, the relevant resolutions and circulars of the IMO and the relevant international testing standards.

- International conventions. International conventions shall mean:
  - The 1966 International Convention on Load Lines (LL66),
  - The 1972 Convention on International Regulations for Preventing Collisions at Sea (COLREG),
  - The 1973 International Convention for the Prevention of Pollution from Ships (MARPOL) and,
  - The 1974 International Convention for the Safety of Life at Sea (SOLAS).

- Testing standards. Testing standards shall mean the standards set by:
  - IMO,
  - The International Organization for Standardization (ISO),
  - The International Electro-technical Commission (IEC),
  - The International Telecommunication Union (ITU),
  - The European Committee for Standardization (CEN),
  - The European Committee for Electro-technical Standardization (CENELEC),

- The European Telecommunication Standards Institute (ETSI) and,
- The USA legislation, regulations and administrative provisions stated on: 46 USC. 3306 and 46 CFR Parts 159 to 165.

The expected contract outcome is a study containing two documentary parts, namely, one for the list of equipment subject to the MED (currently Annex A of the Directive 96/98/EC) and one for the equipment subject to the EU-USA MRA, providing for both lists the update of their respective regulatory provisions during an estimated period of 12 months. For every period of 12 months, the final period duration for studying the standardization progress shall be agreed with the contractor during the kick off meeting. The starting and finishing dates for the 12 months periods will be stated during the kick off meeting with the contractor. The 12 months period can be expected to be established to run from 1 December to 30 November as per the average periodicity of the world wide standardization works for the maritime sector. The said 12 months period encompasses the current frequency of updating the MED Annex A, which draft document is regularly endorsed by the Committee of Safe Seas and Pollution Prevention from Ships within the first quarter of every calendar year.

The study is also expected to gather the contributions of the relevant "Expert Parties" invited to address their comments within an intermediate stage of the study production. For the purpose of this contract "Expert Parties" shall mean:

- European Union Member States.
- European Commission.
- United States of America Coast Guard.
- European Maritime Safety Agency.
- Notified Bodies under MED.
- Standardization bodies: CEN, CENELEC, ETSI and FCC.
- Industry Associations thru their National Administrations or their NB.

To facilitate the provision of the "Expert Parties" contributions the contractor shall set up a dedicated Internet-based application and shall grant temporary access to the "Expert Parties" for them to be able to share on line the documentation of their contributions to the amendment of the list of equipment concerned by the MED under consideration.

2.1 EU Legal implementing act for the updated list of the applicable international instruments and of the requirements and testing standards, as applicable.

The main objective of the Directive is to ensure that marine equipment on EU flagged ships are designed and constructed according to the appropriate standards. In addition to improving safety, it is also expected that constructing equipment to higher standards will improve the competitiveness of the EU ship building industry. The Directive places a number of key requirements on the European Commission. However, some technical specific tasks have been transferred to EMSA. The purpose of this part of the contract is for EMSA to provide technical support to the European Commission in proposing amendments to the list of the applicable international instruments, and of the requirements and testing standards applicable to the equipment subject to the MED.

2.1.1. Article 17 of Directive 96/98/EC and, as of 18 September 2016 and Article 36 of Directive 2014/90/EU are the legal basis empowering the European Commission to update and to amend the list of the equipment subject to the MED (current MED Annex A).

Until 18 September 2016, MED Annex A may be amended in accordance with the procedure laid down in Directive 96/98/EC Article 18. As per MED Article 18, the European Commission shall be assisted by

the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS). The COSS was established as per Regulation (EC) No 2099/2002 of 5 November 2002.

According to Article 36 of Directive 2014/90/EU the European Commission is empowered to adopt delegated acts in accordance with Article 37 in order to update the references to standards, as referred to in Annex III, when new standards become available.

2.1.2. With regard to these Articles the contractor shall produce a study to update the list of the applicable international instruments, and of the applicable requirements and testing standards displayed in MED list of equipment and standards, in order to:

- apply subsequent amendments of international instruments for the purposes of the MED;
- update the above mentioned list, both by adding new equipment and by deleting some others according to the latest IMO Conventions content;
- identify specific standards for the follow up of productions according to the conformity assessment modules (B+D, B+E, B+F, G);
- include the implementing dates according to the information published by the standardization bodies;
- include other standardisation organisations to the ones listed in the definition of “testing standards” given in the MED Article 2 (of both Directives).

2.1.3. The contractor shall identify which regulations and standards in international instruments and which international and European testing standards have been amended or adopted since the latest adoption of the list of the equipment subject to the MED (current Annex A) and which are relevant for the purpose of updating the said list. The contractor shall in particular analyse the need for further improvement of the current Annexes A.1 and A.2 based on the work already achieved in the latest available Commission Directive amending the current Annex A.

2.1.4. The contractor shall identify all the related dates for the regulations and standards in international instruments and which international and European testing standards have been already listed, amended or adopted since the latest adoption of list of the equipment subject to the MED (current Annex A) and which are relevant for the purpose of updating the said list, based on the work already achieved in the latest available Commission Directive amending the current Annex A.

2.2 EU-USA MRA Annex II - Updating of its regulatory provisions.

The purpose of this part of the study is to assist the Commission in its further discussions with the USA concerning the equipment items that could be included in a MRA on marine equipment and/or identify what work could be done in view of establishing equivalence at a later date.

The contractor shall provide a technical analysis in order to identify for which products the EU and USA have introduced standards and/or guidelines for the application of IMO rules and examine the equivalence of such standards and guidelines. The basis for the study will be the MED (as most recently amended), the corresponding regulations of the United States of America Coast Guard (USCG), USA Federal communication Commission (US FCC) and, the international instruments as referred to in article 2 of the MED.

2.2.1. The European Community and the United States of America are referred to as “the Parties” within the Preamble of the EU-USA MRA for marine equipment. The EU-USA MRA Article 7(1) establishes a Joint Committee (JC) consisting of representatives of each Party. The Council Decision 2004/425/EC (21 April 2004) Article 3 appoints the European Commission to represent the European Community in the JC.

The EU-USA MRA Article 7.3 (d) is the legal basis empowering the JC to update and to amend the EU-USA MRA annexes.

2.2.2. The study shall provide a report containing the analysis of equivalence between the EU legislation, regulations and administrative provisions (refer to MED as amended and to the Guide for implementation of Directives based on the New Approach) and the USA legislation, regulations and administrative provisions (refer, at least, to 46 USC 3306 and to 46 CFR Parts 159 to 165).

2.2.3. The report shall contain the analysis of all the current items of the MED, as most recently amended, in relation to the applicable EU and USA provisions for approval. Furthermore an objective conclusion on equivalence shall be provided, in order to be able to decide how to update the current MRA by adding new items within its future scope.

Mutual recognition based on equivalence of technical regulations implies that one can establish equivalence between the respective product regulations, testing standards and conformity assessment procedures in the EU and USA. In general terms this means that different regulatory requirements (including product standards, test methods and conformity assessment procedures) are capable of fulfilling the regulatory objectives of MED, i.e. to enhance safety at sea and improve prevention of marine pollution.

The key to accepting USA regulations and standards, as equivalent to the ones of the EU, is that they give the same assurance in terms of fulfilling EU regulatory objectives. In other words, if the EU prescribes a standard in order to achieve a given level of safety or environmental protection, the USA standard must be capable of ensuring the same level of safety and protection.

Both EU and USA regulations on marine equipment are based on international conventions on marine safety and marine pollution prevention established within the IMO, in particular the SOLAS and MARPOL Conventions, together with the relevant test methods referred to in IMO Resolutions, Circulars, Codes, etc. For some products, both the EU and the US have complemented IMO requirements with European and USA standards respectively. In the case of the MED, European testing standards have been added wherever no international testing standards are available or where European testing standards equivalent to the international ones can be used as an alternative. The USA has also in certain cases complemented IMO requirements with guidelines or other documents of a regulatory nature, for their implementation. Such guidelines can, for example, relate to sampling methods, competence of persons carrying out witnessed testing etc. and are elaborated by the regulatory authorities.

2.3 Deliverables

The contractor shall provide the following deliverables for every 12 months of service:

- A 12-months term action plan.
- An interim report.
- A draft final report.
- A final report.

The 12-months term action plan shall be delivered during the kick-off meeting.

With regard to the expected schedule for the reports delivery, the contractor shall refer to the provisions stated at point 4 of this tender specification.

In order to collect worldwide comments from the “Expert Parties” (refer to point 2), the contractor shall set up an Internet based application. This application will be intended to gather the comments and technical contributions from the Expert Parties. The Expert Parties will be invited to add their comments by using such an Internet based application. The comments will be logged by date in the dedicated Web Site and will be available to be read by all logged-in Expert Parties. The contractor will manage the invitations to provide contributions as per EMSA due instructions. The invitations will be communicated through the Technical Secretariat of the Notified Bodies Group under the MED. The application will be open for comments for a period no shorter than 2 weeks (or 10 working days as per EMSA Calendar) and no longer than 3 weeks (or 15 working days as per EMSA calendar). The contractor shall manage the access permissions to grant the Expert Parties with full reading rights and limited writing rights, so that the contributions belonging to other Expert Parties cannot be deleted. The contractor shall ensure the integrity of the information to prevent inadvertent rub-out of previously collected contributions during the eventual access of the Expert Parties.

In addition, the contractor shall adhere to the editorial features as described at point 2.3.5.

2.3.1. Action Plan.

The action plan shall be outlined for a 12-months term.

The action plan shall contain information concerning the following scheduled milestones:

- Cut-off date for the current 12-month term updating (+/- 1.5 month).
- Meetings proposed to be held between EMSA and the contractor.
- Delivery of the reports.

2.3.2. Interim Report.

The interim report shall contain, at least, the following chapters:

- Part I. Interim study for the updating of MED list of equipment, standards and their implementing dates.
- Part II. Interim study for the updating of EU-USA MRA Annex II.

At this stage of the study the inclusion of regulatory provisions not yet published and any other related information shall be added as “Annex 1” of the Interim Report.

The interim report shall be uploaded to the Internet-based application for Expert Parties comments. The uploading shall be previously authorized by EMSA in due time with regard to the planned progress.

2.3.3. Draft final report.

Following the comments of the Expert Parties and further updating tasks, as carried out during the online consultation periods, a draft final report shall be produced.

The draft final report shall contain, at least, the following chapters:

- Part I. Draft final study for the updating of MED list of equipment, standards and their implementing dates.
- Part II. Draft final study for the updating of EU-USA MRA Annex II.
- Annex 1. Contributions of the Expert Parties invited to address their comments for the amendment of MED Annex A. The contributions shall be listed as per item numbering at MED list of equipment and standards and shall be sorted as per the following priority of presentation:
    - EU Member States.
    - European Commission.
    - Notified Bodies under MED.
    - Standardization bodies: CEN, CENELEC, ETSI.
    - European Maritime Safety Agency.
    - Industry associations.
- Annex 2. Contributions of the Expert Parties invited to address their comments for the amendment of EU-USA Annex II. The contributions shall be listed as per item numbering at EU-USA MRA Annex II and will sorted as per the following priority of presentation:
    - EU Member States.
    - United States Coast Guard.
    - European Commission.
    - Notified Bodies under MED.
    - Standardization bodies: CEN, CENELEC, ETSI and FCC.
    - European Maritime Safety Agency.
    - Industry associations.

At this stage of the study the inclusion of regulatory provisions not yet published and any other information considered relevant will be accepted. New relevant information will be added as per the contractor criteria. If so it will be added as Annex 3 of the Interim Report.

2.3.4. Final report.

Following the Draft Final Report, EMSA will produce comments with regard to the draft Final Report contents and the contributions from the Expert Parties. Then EMSA will send the comments to the contractor. The contractor shall include EMSA's comments into the Final Report.

The Final Report shall solely contain the following chapters:

Executive summary
Part I. Study of MED list of equipment, standards and their implementing dates for its amendment.
Part II Study of EU-USA MRA Annex II for its amendment.
Annex 1. List of all the technical standards included in the study with explicit reference to all their related implementation dates and stability date as stated/foresee by their standardization bodies.

The executive summary shall describe the methodology used to develop the Final Report and shall include recommendations to eventually enhance updating for the following 12 month term.

Part I and Part II shall have the structure of the most updated legal text used as basis for the updating. If new categories of equipment are added, they will be included in a new point properly numbered. Both Part I and Part II of the Final Report shall not include reference to regulatory provisions not yet published.

For Part I, the former introduction or withdrawal of pieces of equipment already included into the MED (notably movements from the current MED Annex A.1 to the current MED Annex A.2 and from MED Annex A.2 to MED Annex A.1) shall not be specified. These "former movements" refer to the previous amendments of MED list of equipment and standards stated into the respective Commission Directives

amending the Marine Equipment Directive. Only new introduction or withdrawal of pieces of equipment shall be stated in the study. Furthermore, during the study this kind of lately moved equipment shall be labelled using the appropriate numbering (similar to current “Ex A.1/x.xx” or Ex A.2./x.xx”) and the statement shall be written at the cell containing the item number within the following carriage return. The numbering system shall be kept as is for ensuring the equipment traceability as per the current codes of the public list for approved equipment as currently published at the MarED database.

For Part I, in a first instance, the new equipment shall be included in the proposal and labelled as “New item”. The label “New item” will be added in the cell containing the item number.

For Part II, the equipment eventually removed from previous versions of the EU-USA MRA shall be labelled as “Deleted from the EU-USA MRA from “date” to “date””.

Annex 1 of the Final Report shall list all the technical provisions included in the final draft issued by EMSA to COM by the end of every September. The technical standards in Annex 1 of the Final Report shall be provided in tables both in paper hardcopy and electronic format, preferably as Excel tables. The contents of the tables will be suitable for exporting them to become tables for a data base of standards. Thus special care shall be taken to identify tables’ primary key, the correspondent tables’ foreign key and the relationship among tables. These tables shall contain all the information present in list of equipment and standards of MED and in particular the alphanumerical code used, the year of publication, reference to the MED item number affected and title of the standard reference shall be also quoted.

2.3.5. Editorial features for Part I and Part II of the reports.

With regard to the edition of the Parts I and II of the reports (interim, draft final and final), the contractor shall adhere to the following editorial features:

The text font shall be “Verdana”; font style regular; size 10.

No bold font shall apply.

The cover sheet of the report can be formatted as per contractor design.

The tables containing the items information of the Annexes shall have the same layout as the current tables in the MED list of equipment and standards or the MRA Annex II, as applicable. No addition of extra columns shall be done.

The technical regulations in the tables shall be written so that they can be read as a piece of regulation per line and the line will start with a dash (-).
Example:
-IMO Res.A 694(17),
-IMO Res.MSC.48(66)-(LSA Code).

If the same technical provision is stated with regard to two different parts of the provision, these different parts shall be written in different lines.
Example: Parts I and V of the LSA code will be quoted as:
-IMO Res.MSC.48(66)-(LSA Code) I,
-IMO Res.MSC.48(66)-(LSA Code).V.

Inside the same cell, the provisions in different lines will have a comma (,) at the end of line and a full stop (.) at the end of the last technical provision.

Example: In a given cell containing 4 technical provisions, such provisions shall be separated as follows:

-Reg. II-2/10,
-Reg. V/19,
-IMO Res.A694(17),
-IMO Res.MSC.116(73).

The list of provisions inside the same table cell shall be written following the priority below, in ascending order and quoted as per structure provided:

Technical provision	Quoted as per the following pattern
SOLAS Regulations	-Reg. Chapter/RegulationNumber
IMO Assembly Resolutions	-IMO Res.A.Number(Assembly)
IMO MSC Resolutions	-IMO Res.MSC.Number(Session)
IMO MSC Resolutions referring a code	-IMO Res.MSCNumber(Session)-(Code name) Part/Chapter
IMO MSC Circulars	-IMO MSC/Circ.(Number)
ETSI ETS Standards	-ETSI ETS Number VersionOrEdition (Year-Month)
ETSI EN Standards	-ETSI EN Number VersionOrEdition (Year-Month)
EN Standards	-EN Number (Year)
EN ISO Standards	-EN ISO Number (Year)
ISO Standards	-ISO Number (Year)
IEC Standards	-IEC Number (Year)

Examples

Technical provision	**Example**	**Note the "Space" between**
SOLAS Regulations	-Reg. II-2/10, -Reg. V/19.	"-Reg." and Chapter
IMO Assembly Resolutions	-IMO Res.A694(17).	"-IMO" and "Res…"
IMO MSC Resolutions	-IMO Res.MSC.116(73).	"-IMO" and "Res…"
IMO MSC Resolutions referring a code	-IMO Res.MSC.48(66)-(LSA Code) I.	a)"-IMO" and "Res…" b) Code name and Part/ Chapter
IMO MSC Circulars	-IMO MSC/Circ.(862).	"-IMO" and "Res…"
ETSI ETS Standards	-ETSI ETS 300460 Ed.1 (1996-05)	a) "-ETSI" and "ETS" b) "ETS" and Number c)Number and VersionOrEdition d) VersionOrEdition and (Year-month)
ETSI EN Standards	-ETSI EN 300828 V1.1.1 (1998-03).	a) "-ETS" and "EN" b) "EN" and Number c)Number and VersionOrEdition d) VersionOrEdition and (Year-month)
EN Standards	-EN 60945 (2002).	a) "-EN" and Number b) Number and (Year)
EN ISO Standards	-EN ISO 9875 (2001).	a)"-EN" and "ISO" b) "ISO" and Number c) Number and (Year)
ISO Standards	-ISO 22090-1 (2002).	a) "ISO" and Number b) Number and (Year)
IEC Standards	-IEC 60945 (2002).	a) "IEC" and Number b) Number and (Year)

EMSA shall be entitled to request the contractor to implement further editorial features at any stage of the project.

2.4 External contributions and comments of Expert Parties.

2.4.1. The contractor shall take due account of the requests, suggestions and comments as provided by the Expert Parties, namely:

European Union Member States.
European Commission.
United States of America Coast Guard.
European Maritime Safety Agency.
Notified Bodies under MED.
Standardization bodies: CEN, CENELEC, ETSI and FCC.

2.4.2. The consideration of comments will also include the pieces of equipment which are not yet dealt with in the MED.

2.4.3. The planning, execution and progress of this part of the study shall ensure that the core debate can take place on line and that every contribution will be noted and included in the study. To do that, the contractor shall set up an Internet based application intended to ease the inclusion of contributions by the Expert Parties. The contractor and EMSA shall agree on the schedule and the time slots to accept contributions to the ongoing work.

2.4.4. The contractor shall invite the Expert Parties to participate in the Internet forum for providing contributions. The invitation will be carried out through the Secretariat for the Group of Notified Bodies under the MED.

2.4.5. The contractor shall include in the Draft Final Report a chapter containing all the contributions received from the Expert Parties invited to participate in the Internet application. The contributions logged shall be listed as per the item related number in the regulatory Annexes. The contractor shall state which Expert Parties' contributions he agrees with and then provide supporting arguments to be included in the draft of the forthcoming amendment of the regulatory Annexes. The contractor shall state which Expert Parties' contributions he does not support and will provide a documented justification about the objections to the Expert Party contribution.

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 expected reports and meetings are addressed by the currently implemented methodology for the yearly update of MED list of equipment, standards and their implementing dates.

The methodology for the yearly update of MED list of equipment and standards is currently implemented by EMSA and as a result the following MED Amendments have already been published in the Official Journal of the European Union:

- 4th Amendment was published on 1 July 2008;
- 5th Amendment was published on 6 April 2009;
- 6th Amendment was published on 22 November 2010.
- 7th Amendment was published on 15 September 2011;
- 8th Amendment was published on 10 November 2012;
- 9th Amendment was published on 14 November 2013
- 10th Amendment was published on 25 July 2014

EMSA issued the draft text for the 11th Amendment to the European Commission for COSS' consideration on 03 September 2014. The publication of the 11th Amendment may reasonably be expected before the end of 2015 as its text was endorsed by COSS at its in November 2014.

Following the publication of the new text for the Marine Equipment Directive 2014/90/EU on 28 August 2014, repealing the Directive 96/98/EC on 18 September 2016, EMSA initiated the works for the preparation of the 12th Amendment on 1 October 2014 with a view to enhance the current information of MED list of equipment and standards for the certification of the equipment. That enhancement considers the inclusion of explicit dates of applicability and expiration dates of product certificates for every single piece of equipment into the current MED list of equipment and standards. Regarding this addition of information the final draft for the 12th amendment will be discussed by the EU MS in February 2016, so that the repealing date for the legal basis and the date of publication of the new technical annex (to be based upon the draft 12th amendment) will coincide in September 2016.

The current methodology shows that the text for amendments of the MED list of equipment and standards is endorsed by the European Commission approximately during the first quarter of the year and following the transmission of the draft text by EMSA to European Commission at the end of September.

The current technical specification for the contract must, consequently, intend to ensure the continuity of the current methodology. Thus, the delivery of expected reports and the working meetings shall be scheduled to match, as stated below.

4.1. Expected reports.

For every yearly period of the study, the Contractor shall submit the following reports within a 12 month contractual period:

- Interim Report (March – April, concerning only MED).
- Draft Final Report (May – June: for on line consultation on MED list of applicable standards).
- Final Report (October – November: including the study for MRA Annex II).

Three copies of the reports shall be supplied in paper form and one copy in electronic form in MS Word format.

4.2. Foreseen meetings

For every yearly period of the study, the contractor is expected to hold 4 meetings:

- Kick off Meeting (first quarter of the calendar year, following the COSS meeting in a location deemed most suitable, within the EU).
- Interim Report Review Meeting (March - April, in Lisbon, Portugal).
- Draft Final Report Review Meeting (after on-line consultation by June-July, in Lisbon, Portugal).
- Expert meeting (July, in Brussels, Belgium). This meeting will be eventually held with the participation of EU Member States Experts and USCG Experts in Brussels, Belgium. The contractor may be asked to attend this additional meeting to assist EMSA.

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 contract is assessed at 130 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 **520,000** 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**[2] available on the Procurement Section under the call to tender EMSA/OP/04/2015 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 criteria[1]. 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)

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.

[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 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

- The price for a 12 month period shall include a study on the yearly updates of the regulatory provisions for the certification of the marine equipment subject to the Marine Equipment Directive, as amended, (Council Directive 96/98/EC and, as of 18 September 2016, Directive 2014/90/EU) and listed in Annex II of the EU-USA Mutual Recognition Agreement (Council Decision 2004/425/EC).It shall also include the consultant availability on line for consultation purposes with the EU MS Administrations and with the USA Administration:

  The price (for every 12 month period of service) shall include four 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 will evaluate the technical and professional capacity of the potential contractor against the criteria below. Thus, the tenderer shall include in its tender the information required below, and the necessary documentary evidence for the following aspects:

I. 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 the subject matter of this tender.

  Tenderers should provide with their bid 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 and the EU-USA MRA. 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 on line consultation for a number of stakeholders not larger than 35 parties.

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

II. 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 approach to the project management.
2. Quality criterion 2, Q_2. ($W_2 = 20$ %): Access to relevant data and proposed resources for the necessary consultation on line,
3. Quality criterion 3, Q_3, ($W_2 = 40$ %): Description of the current starting point for the study.

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

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

The overall weighted quality is

$$Q = \sum_i Q_i * W_i$$

The score for quality is

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

The score for price is

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

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 approach to the project management. This may include detailed proposals of how the project as a whole would be carried out (draft a 12-months term action plan), and by whom (named individuals), including key milestones, deliverables and a description of the technical standardization progress and their relevant dates of applicability.

- Quality criterion 2 (20 %). Access to relevant data and proposed resources for the necessary consultation on line. The bid must show the methodology to be applied for the specific issue of obtaining, comparing, assessing (to include, to replace, or to disregard) and sharing data necessary for the successful completion of this study. It shall also include a description on how the tenderer would justify the inclusion/removal of a particular testing standard and also the source of its cycle of life dates. Regarding the standardization bodies, the bid should include an explanation of the meaning of “Date of Withdrawal” and quote the relevant sources of information.

- Quality criterion 3 (40 %). Description of the current starting point for the study. That description shall be demonstrated in a short presentation aimed to answer the questions below.

    1. Find out the relevant MED provisions that serve as legal basis for addressing the amendment of MED list of equipment, standards and their implementation dates; to which EU institution it is addressed, what is the scope of the amendment, and what are the restrictions that need to be respected by that EU Institution in application of the legal basis, when MED list of equipment, standards, and their implementation dates are proposed to be amended.
    2. What has been the legal act which has been published in the OJEU following the adoption of the text for the amendment of MED Annex A until 2014?
    3. Refer to the text of the 5th Amendment of MED Annex A Commission Directive "2009/26/EC" and to the text of the 6th Amendment of MED Annex A Commission Directive "2010/68/EU". Please explain why a reference code for the mentioned Directives refers to EC and the other to EU.
    4. Refer to the text of the 9th Amendment of MED Annex A Commission Directive 2013/52/EU. Explain the meaning and scope of the notes (b) of Annex A.1.
    5. Refer to the text of the 6th Amendment of MED Annex A Commission Directive 2013/52/EU. Explain what are the common elements in all the regulations quoted under column 3 for the clause 1 "Lifesaving appliances"?
    6. Refer to the text of the 6th Amendment of MED Annex A Commission Directive 2013/52/EU. Explain what are the common elements in all the regulations quoted under column 4 for the clause 1 "Lifesaving appliances"?
    7. Refer to the text of the 9th Amendment of MED Annex A Commission Directive 2013/52/EU. What are intended the testing standards under column 5 intended for?
    8. Explain under which circumstance it would be possible to refer to standards for the purpose of the follow up of series productions in factories under column 5 of MED Annex A Commission Directive 2013/52/EU.
    9. Explain why it is not necessary to quote amending documents to those already listed in MED Annex A in the text of any amendment of MED Annex A. What is the legal basis in the Directive 96/98/EC for being able to do that?
    10. Refer to Annex A.2 of MED Annex A 9th amendment. Why are these pieces of equipment in a different section of Annex A? To which MED stakeholder is Annex A.2 addressed?

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.