



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2015
EMA/772990/2014

Questions and answers relating to procurement procedure: provision of internal audit services– EMA/2014/49/AUD

Table of contents

Questions and answers	2
-----------------------------	---



Questions and answers

No.	Question	Answer
1	Will the majority of the audit work take place within your Canary Wharf office and what is the approximate split between UK and European based audit work?	All audit work will take place at the Canary Wharf office.
2	Is there scope for amending the terms and conditions within the Service Contract? Our legal team would not let us sign up to what is currently in there so just wanted to check that there is room for negotiation on this.	As indicated in point 7 of the invitation to tender letter submission of a tender automatically implies acceptance of all the terms and conditions stipulated in the invitation to tender, the current technical specifications and annexes including the draft contract. Tenderers must confirm acceptance of the draft contract and terms and conditions of the tender as part of the tender response. No negotiations shall be entered into on the draft contract terms. Should a tender require a clarification, this can be made but this shall not lead any alteration of the draft contract.
3	Can you please confirm what level of information is required in response to question 13.1, will a copy of our professional risk indemnity insurance be sufficient?	Yes, the copy of the professional risk indemnity insurance is sufficient.
4	In the 'Draft Framework service contract' document under Article I.3 – Contract Price, Paragraph I.3.1, you state the maximum amount of the contract shall be EUR 480,000. Is this the total value for the full 4 year contract period, or an annual spend value?	This is the total value for the 4-year contract period

No.	Question	Answer
5	In the 'Specifications for open invitation to tender', Paragraph 3.4 refers to 'Financial audits' and specifically to express of an opinion. This appears to be consistent with the scope of work for the external auditor and a potential duplication of effort. Could you please clarify the scope of work for this section – audit of the reportable numbers v controls analysis? Could you provide an overview of the expected output from these audits?	The Agency's internal audit may conduct audits in any area, including financial activities and an opinion on the audited area is a requirement. Internal financial audits tend to be targeted in specific areas and to look at accounts and procedures in a more detailed way than an external audit, whose goal is to analyse the entire annual accounts. External auditors may take this work into account when determining risk level and deciding testing procedures in each area, in line with ISSAI 1610 and ISA 610 http://www.issai.org/media/13128/issai_1610_e.pdf
6	In your 'Questions and answers relating to the procurement procedure: provision of internal audit services – EMA/2014/49/AUD', the responses to question 2 is categorical in relation to negotiations about the terms of the draft contract. Having reviewed the terms in detail, there are a number of conditions that will be difficult to accept in their current state and may impact the ability to submit a proposal. Could you please confirm if there are any opportunities to negotiate conditions? Is the non-negotiable position on the draft contract a 'deal breaker'?	As indicated in point 7 of the invitation to tender letter submission of a tender automatically implies acceptance of all the terms and conditions stipulated in the invitation to tender, the current technical specifications and annexes including the draft contract. Tenderers must confirm acceptance of the draft contract and terms and conditions of the tender as part of the tender response. No negotiations shall be entered into on the draft contract terms. Should a tender require a clarification, this can be made but this shall not lead any alteration of the draft contract.