CLARIFICATIONS to CONTRACT NOTICE and TENDER DOSSIER

Contract Title: **Provision for Approved Laboratory Test Result**

Publication Reference: SIHHAT/2021/SUP/INT/01

CN: Contract Notice
TD: Tender Dossier
DOC: Document
ART: Article
DC: Draft Contract
ITT: c4b_itt_en [Instructions to Tenderers]*
TS: c4f_annexiitechspeciiitechoffer_en [Annex II + III: Technical Specifications + Technical Offer]*
GC: General Conditions
SC: c4d_specialconditions_en [Special Conditions]*
App.: Appendix

** In-parenthesis parts show the title inside the documents.*

Further to the requests received from the tenderers, the following clarifications are provided.

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Contract Notice					
1	CN	6.	The contract aims to cover the laboratory test needs of 900 Migrant Health Units within the SIHHAT-2 Project. Indicatively 11.127.883 laboratory test results are targeted within the scope of this contract. The laboratory costs of E/MHCs will be covered by this contract till 30.11.2023…	The number of centers is specified as 900 in the tender specification but we see it as 179 centers in total on the Appendix 1. Could you please clarify it with more detail?	Within the SIHHAT-2 Project, there are totally 179 Enhanced/Migrant Health Centers (E/MHCs), these centres comprise ofoverall 900 Migrant Health Units.There is difference between the term “unit” which refers to sections inside the

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					centres and "centre" which refers to centre itself.
2	CN	15.	The implementation period of the contract will lasts till 30.11.2023, starting from the date of signature of the contract by both parties…	What is the starting time for this Project?	Please see Article 2 of Instructions to Tenderers (ITT) for provisional dates.
3	CN	16./ 3.a.	The tenderer has delivered laboratory test results under at most 3 (three) contracts with a budget of at least one-fourth (¼) of its financial offer.	This item requires the tenderers to prove that they have delivered laboratory test results under at most 3 (three) contracts with a budget of at least one-fourth (1/4) of its financial offer. In this context, could you please clarify if we have understood correctly: If a tenderer's financial offer is (theoretically) € 1 million, does this mean that the tenderer - must present 3 separate contracts related to delivery of laboratory test results, each with a budget of at least € 250 thousand? OR - must present maximum 3 contracts which add up to a total of € 250 thousand.	Within the scope of a maximum of 3 contracts, the tenderer should delivered laboratory test result services, grand total of which should be at least 1/4 of financial offer.
4	CN	17	Award criteria: Price	The award criteria is "price" only. We understand that according to PRAG heading 4.3.3 that the award criteria for supply contracts is "price or, in exceptional cases mentioned in Section 4.3.3.3., the best price-quality ratio. We would like to note that this is a highly complex project that requires particularly significant ancillary services, as described under Section 4.3.3.3. of PRAG. As an experienced operator in the field, we are concerned that not applying quality criteria in this particular tender might create additional risks in terms of implementation and might jeopardize the achievement of the project's results.	Within the scope of this tender; award criteria applied to technically compliant tenders is price.

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				Therefore, we would kindly ask the Contracting Authority whether including price-quality ratio criteria to the evaluation, in addition to the technical checks done in the yes/no format, could be considered.	
5	CN	16.	3) Technical capacity of tenderer (based on i.a. items 5 and 6 of the tender form for a supply contract). The reference period which will be taken into account will be the last 5 (five) years preceding the submission deadline. a. The tenderer has delivered laboratory test results under at most 3 (three) contracts with a budget of at least one-fourth (¼) of its financial offer.	Could you please give us more detail about technical capacity of tenderer? It means work experience? If we are we able to provide 1 contract instead of 3 cotract that fulfilling the same financial requirements (¼)? It is acceptable for you? If we work with sub contractor it has be provide 3 contacts as well as tenderer? What is the partial completion rate for projects with ongoing contact? Is private sector contract accepted?	Please see Answer 3 of the Clarifications to CN and TD. Maximum 3 contract means; either 1 or 2 or 3. Please see Article 2.6.11.3 of the PRAG (practical guide on contract procedures for European Union external action) *"… Candidates/tenderers are allowed to refer either to projects completed within the reference period (although started earlier) or to projects not yet completed.* *Only the portion satisfactorily completed during the reference period (although started earlier) will be taken into consideration.* *This portion will have to be supported by documentary evidence (statement or certificate from the entity that awarded the contract or proof of final payment) also detailing its value. If a candidate/tenderer has implemented the project in a consortium, the percentage that the candidate/tenderer has completed*

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					must be clear from the documentary evidence, together with a description of the nature of the services, supplies or works provided if the selection criteria relating to the pertinence of the experience have been used…"
6	CN	16.	…	The economic and financial, professional capacity and technical capacities required from tenderers in previous contract (SIHHAT/2017/SUP/INT/03) were determined as such: • The average annual turnover of the tenderer who submitted an offer must exceed 3,000,000 EUR. • The tenderer has delivered supplies under at most 3 contracts with a total budget of at least 3,000,000 EUR in the fields relating to the provision of laboratory test result which were implemented last 5 years from the submission deadline. However, in the new contract we notice that nearly these criteria were reduced by nearly two thirds. We fear that such drastic reductions in the selection criteria might create additional risks, in that a contractor with very limited experience might not be able to carry out the activities of this project in line with EU standards.	Each tender is typical the conditions of which are determined based on the current circumstances. This is a specific tender within another project namely.SIHHAT II. Please be informed that all the procurement rules and general principles are being perfectly followed during the EU procurement procedures within SHHAT-II project.
Instruction of Tenderes (ITT)					
7	ITT	1./ 1.1.	… Collecting samples from patients shall be performed on every working day until 11.30. The samples shall be ready for testing/examination at the laboratory between	The samples will be collected from patients every working day until 11.30 am. Samples will be collected **between 11.30 and 14.00** and transferred to the laboratory where they will be studied, and be prepared for examination within a minimum of 24 hours and maximum 36 hours, and	Please see Corrigendum to TD

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			11.30 a.m. and 14.00 and results shall be reported by 14.00 on the next day (within maximum 24 hours) (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records should be submitted to the Inspection and Acceptance Commission. The contractor should transport the samples satisfying the cold chain conditions and report the results within the below mentioned time period. …	the results will be reported within a maximum of 24 hours after the samples arrive at the laboratory (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records submitted to the Inspection and Acceptance Commission. The contractor must transport the samples in a way to meet the cold chain conditions and report the results within the time specified below.	
8	ITT	3	…	We understand from various documents that if the Contractor offers to this tender with subcontractors, the subcontractors must: - satisfy items 3.1 and 3.2 of the Instruction to Tenders document, - not be in a situation defined under the exclusion criteria, - must have a Biochemistry and/or Microbiology Laboratory and License in the Related Field within the scope of the Regulation on Medical Laboratories. 1) The nature of this contract requires the use of both biochemistry and microbiology laboratories. We kindly ask the Contracting authority to consider changing the phrase "and/or" to "and". 2) Based on our experience in implementing the previous project in the last three years, we are of the opinion that all tenderers, regardless of whether they are offering with or without subcontractors, must also have their own valid license for operating a biochemistry and microbiology laboratory. Otherwise, we are concerned that the contract may be awarded to a tenderer without any experience in	It will remain unchanged.

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				laboratory services. This is a considerable risk in terms of organization and management, even for tenderers who have subcontracting relations with such laboratories. 3) Our experience in the implementation of the previous contract has shown that it is critical for subcontractors to meet the same quality criteria required from tenderers, and as such, we would like to ask Contracting Authority to: - confirm whether subcontractors are required to meet other quality specifications laid down in the tender documents, such as those related to device specifications, staff qualifications and expertise documents etc., and - confirm whether tenderers are required to submit their subcontractors' proof documents in their offers.	
9	ITT	10.2	All tenders must be submitted in one original, marked 'original', and three copies signed in the same way as the original and marked 'copy'.	All tenders must be submitted in one original, marked 'original', and three copies signed in the same way as the original and marked 'copy'. Do the documents required to be marked as "copy" need to be certified by the notary.	Please revisit the document and make sure if spesifically certification of the notary required. If there is not such a requirement, there is no need for the certification. If so, please submit the documents as certified.
10	ITT	11./ 11.3.10	The tenderer shall provide current and valid certificate for the Quality Management System. (e.g. ISO 9001:2015 or etc.)	It states under this item that the tenderer shall provide current and valid certificate for the quality management system and refers to ISO 9001:2015 as an example. Would you kindly clarify whether the term "valid" should be understood that the certificate proving the tenderers' quality management system should be received from a duly accredited conformity assessment body recognized within the EA, ILAC and IAF system?	As of the date of deadline for submission of tenders, the validity period of the document to be submitted must not have expired and the certificate should be in-date.
11	ITT	11./ 11.3.10	The tenderer shall provide current and valid certificate for the Quality Management System. (e.g. ISO 9001:2015 or etc.)	All laboratory work under this project will be carried out specifically by medical laboratories, and experience shows that it is crucial for the contractor to meet particular	The requested document is related to the management system of the

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				requirements that go beyond the requirements laid down in general quality management standards (for example EN ISO 9001:2015), and be able to meet the quality and competence criteria specified under EN ISO 15189:2012 Medical Laboratories – Requirements for quality and competence. We kindly ask the Contracting Authority to clarify whether the contractor is required to have a valid certificate for EN ISO 15189 as well.	tenderer. It will remain as it is. No changes will be made.
Draft Contract (DC)					
12	DC	1./ 1.1.	… Collecting samples from patients shall be performed on every working day until 11.30. The samples shall be ready for testing/examination at the laboratory between 11.30 a.m. and 14.00 and results shall be reported by 14.00 on the next day (within maximum 24 hours) (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records should be submitted to the Inspection and Acceptance Commission. The contractor should transport the samples satisfying the cold chain conditions and report the results within the below mentioned time period. …	The samples will be collected from patients every working day until 11.30 am. Samples will be collected **between 11:30 and 14:00** and transferred to the laboratory where they will be studied, and be prepared for examination within a minimum of 24 hours and maximum 36 hours, and the results will be reported within a maximum of 24 hours after the samples arrive at the laboratory (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records submitted to the Inspection and Acceptance Commission. The contractor must transport the samples in a way to meet the cold chain conditions and report the results within the time specified below.	Please see Corrigendum to TD
Special Conditions (SC)					
13	SC	10.1.	All goods purchased must originate from an eligible source country as defined in a	"All goods purchased must originate from an eligible source country as defined in a Member State of the	This is a template document and does not subject to any modifiations.

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			Member State of the European Union or a country covered by the IPA II programme. For these purposes, 'origin' means the place where the goods are mined, grown, produced or manufactured. The origin of the goods must be determined according to the EU Customs Code or to the relevant international agreement applicable.	European Union or a country covered by the IPA II programme" However, INSTRUCTIONS TO TENDERERS 3.1. Stipulates "However, they may originate from any country when the amount of the supplies to be purchased (as a whole or, if divided into lots, per lot) is below EUR 100 000. " How should the prospective	Therefore, this article will remain unchanged.
General Condition (GC)					
14	GC	26/ 5.a	26.5. The payments shall be made as follows: a) 40% of the total contract price after the signing of the contract, against provision of the performance guarantee and of a pre-financing guarantee for the full amount of the pre-financing payment, unless otherwise provided for in the special conditions. The pre-financing guarantee shall be provided to the contracting authority following the procedure foreseen for the performance guarantee in accordance with Article 11.3-5, and in accordance with the format annexed to the contract. The pre-financing guarantee must remain valid until it is released 30 days at the latest after the provisional acceptance of the goods. Where the contractor is a public body, the obligation for a pre-financing guarantee may be waived depending on a risk assessment made.	It is stated that 40% of the contract price may be paid against a pre-financing guarantee, unless it is stated otherwise in the special conditions, however, this condition is excluded from the scope in SPECIAL CONDITIONS, Article 26 General Principles for payments. Can the pre-financing amount payment be applied in the scope of the financing of the investments required for the tender.	Payments are scheduled on a monthly basis by the Contracting Authority considering the nature of this contract.

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Annex II + III: Technical Specifications + Technical Offer (TS)					
15	TS	4.1	4.1. The Inspection and Acceptance Commission to be recommended by the provincial directorate of health and to be formed upon the approval of the administration shall be in charge of controlling the work in every province where the relevant laboratory is located. The Commission shall comprise five members including at least one medical microbiology and at least one medical biochemistry specialist on board.	Gives the definition of the Inspection and Acceptance Commissions to be established by the Public Health Directorates in each province. Will the companies have to visit the commission on the site every month and follow the documents face to face regarding the documents they need to submit and get approval during the tender process? Are approval processes subject to a specific calendar?	Please see Annex II: Technical Specifications, which includes sufficient details in the questioned sense.
16	TS	4. / 4.3.1 and 4.3.2	4.3. The tenderer can provide the laboratory test results to be rendered in the provinces specified in Annex-1 through laboratories it shall establish at provincial and/or regional level, or through sub-Contractor(s). 4.3.1. If the Contractor offers to this tender with subcontractors; The laboratory/laboratories to be contracted by the Contractor should have a Biochemistry and/or Microbiology Laboratory License in the related field within the scope of the Regulation on Medical Laboratories. 4.3.2. If the Contractor offers to this tender through provincial or regional laboratory/laboratories; It should establish/prepare laboratory/laboratories and obtain their licenses in accordance with the Regulation on	Is a single licensed laboratory information sufficient in the tender dossier? Or is it required for all regions lab.? Should the licensed laboratory information be submitted in the prequalification file? Sub-contactor (licensed lab.) need to provide all documents as tenderer?	It will be required for all laboratories which are established and/or to work together. Please see Article 4.3.1. and 4.3.2. of the Annex II: Technical Specifications and Article 3. of the ITT both of which provides sufficient information in the questioned sense.

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			Medical Laboratories meeting all requirements of physical condition, personnel, equipment and documentation at the premise (s) it shall designate until the start date of the work. The Contractor can receive services from a subcontractor(s) until its own laboratory obtains a license.		
17	TS	4.6 and 4.7	4.6. Time of delivering results should comply with the table below for all samples regardless of how it is provided by the Contractor. 4.7. Collecting samples from patients shall be performed on every working day until 11.30. The samples shall be ready for testing/examination at the laboratory between 11.30 a.m. and 14.00 and results shall be reported by 14.00 on the next day (within maximum 24 hours) (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records should be submitted to the Inspection and Acceptance Commission. The contractor should transport the samples satisfying the cold chain conditions and report the results within the below mentioned time period.	In the previous contract under the SIHHAT project (SIHHAT/2017/SUP/INT/03), the 24 hour limit started "after the sample arrived at the laboratory". In this contract, however, we understand that the time limits specified do not take into consideration the time spent for the transfer of samples to the laboratory, as item 4.7 specifically states that "The samples shall be ready for testing/examination at the laboratory between 11.30 a.m. and 14.00 and results shall be reported by 14.00 on the next day (within maximum 24 hours). Furthermore, the maximum time of result reporting for Thalassemia tests and Microbiological culture/antiprogram tests have been reduced from 4 to 3. Our experience shows that even under the previous contract, which was more flexible, we required the services of four separate laboratories (some being subcontractors) situated specifically in regions highly populated by immigrants. The new rules, which are stricter, might require our company to seek and additional subcontractors in the region. In this context, we would kindly ask whether the Contracting Authority expects the tenderer to provide a minimum number of laboratories (owned by the tenderer or subcontractor), and whether the Contracting Authority will	Please see Corrigendum to TD.

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				take into consideration the geographical location of these laboratories.	
18	TS	4./ 4.7	Collecting samples from patients shall be performed on every working day until 11.30. The samples shall be ready for testing/examination at the laboratory between 11.30 a.m. and 14.00 and results shall be reported by 14.00 on the next day (within maximum 24 hours) (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records should be submitted to the Inspection and Acceptance Commission. The contractor should transport the samples satisfying the cold chain conditions and report the results within the below mentioned time period.	The samples will be collected from patients every working day until 11.30 am. Samples will be collected between 11:30 and 14:00 and transferred to the laboratory where they will be studied, and be prepared for examination within a minimum of 24 hours and maximum 36 hours, and the results will be reported within a maximum of 24 hours after the samples arrive at the laboratory (excluding thalassemia and microbiological culture/antibiogram tests). Sample delivery times should be recorded and records submitted to the Inspection and Acceptance Commission. The contractor must transport the samples in a way to meet the cold chain conditions and report the results within the time specified below.	Please see Corrigendum to TD.
19	TS	11./ 11.8.	The Contractor should monthly report the number of tests run by the external laboratory/laboratories it commissioned to the Inspection and Acceptance Commission. The number of tests run by the external laboratory on a monthly basis shall not exceed 20% of the total number of tests for the respective month.	Could you revize the item as "The contractor must notify the Inspection and Acceptance Commission on a monthly basis of the number of tests performed by the external laboratory and/or laboratories that they have assigned. In case of agreement with an external laboratory thet meets the same conditions in order to give faster results in provinces where the number of tests is high during the contract period, the inspection acceptance commission should be notified."?	The item will remain unchanged.
20	TS	7./ 7.12.	… The Contractor shall provide catalogues for technical information about the devices to be installed and kits to be worked with, clearly indicate names of manufacturing companies	Could you revize the item as "… The contractor will provide catalogs for technical information on the devices to be installed and the kits to be worked on, clearly stating the names of the manufacturing companies and this information will be available in the tender file."?	It will remain unchanged.

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			and this information shall be presented in the tender dossier.		
21	TS	7.12	The devices to be installed should not complete 10 (ten) years by the end of the term of the contract. The Contractor shall provide catalogues for technical information about the devices to be installed and kits to be worked with, clearly indicate names of manufacturing companies and this information shall be presented in the tender dossier.	Stipulates "The devices to be installed should not complete 10 (ten) years by the end of the term of the contract. The Contractor shall provide catalogues for technical information about the devices to be installed and kits to be worked with, clearly indicate names of manufacturing companies and this information shall be presented in the tender dossier." The device age limit has been increased to 13 years in the Service Procurement tenders applied in our country. Is there any chance of increasing the device age to 13 years in this tender also?	Please see Corrigendum to TD.
22	TS	8.2	The Contractor should make regular internal quality controls for all tests on at least 2 (two) levels every day and be a member to an external quality control program (of approved organizations) for all tests within the scope of work.	"The Contractor should make regular internal quality controls for all tests on at least 2 (two) levels every day and be a member to an external quality control program (of approved organizations) for all tests within the scope of work." However, there is no explanation on the test groups for which an external quality control program cannot be obtained and the manual microbiyological culture tests for which internal quality control cannot be applied.	Please see Corrigendum to TD.
23	TS	8.5	Sample acceptance and rejection criteria should be defined and implemented. The purpose is to inform both the laboratory personnel and other related E/MHC personnel about the rules on sample acceptance to obtain accurate results from the tests and minimize preanalytical errors in particular. A Test Manual including times of sample processing, sample types, information about the tests	It is stated in this item that "The Contractor shall be responsible for translating and distributing introductory brochures prepared by the Administration." Could you please clarify - The number of introductory brochures the Administration plans to prepare during the implementation of the contract, and - whether the Contractor is responsible for the printing of the introductory brochures as well.	Please see Corrigendum to TD

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			which require preliminary preparation, sample acceptance or rejection criteria etc. shall be available. The Contractor shall be responsible for translating and distributing introductory brochures prepared by the Administration.		
24	TS	8.8. and 8.5.	8.5. Sample acceptance and rejection criteria should be defined and implemented. The purpose is to inform both the laboratory personnel and other related E/MHC personnel about the rules on sample acceptance to obtain accurate results from the tests and minimize preanalytical errors in particular. A Test Manual including times of sample processing, sample types, information about the tests which require preliminary preparation, sample acceptance or rejection criteria etc. shall be available. The Contractor shall be responsible for translating and distributing introductory brochures prepared by the Administration. 8.8. Instructions shall be in effect for sample collection and safe transfer. Instructions shall be prepared for sample transfer (indicating acceptable temperature, time, container etc.). Personnel should be delivered training on sample transfer and training should be recorded.	Would you kindly clarify: - which languages the Test Manuals under item 8.5 will be prepared in. - which languages the introductory brochures under item 8.5 will be translated into. - Which languages are required for the instructions and trainings related to the collection of samples, under item 8.8.	Please see Corrigendum to TD.
25	TS	11.4	The Contractor is responsible for fulfilling all legal processes and bearing all expenses with regard to the submission to the reference laboratory of the tests to be verified as a result of HCV, HIV etc. analysis.	"The Contractor is responsible for fulfilling all legal processes and bearing all expenses with regard to the submission to the reference laboratory of the tests to be verified as a result of HCV, HIV etc. analysis." To facilitate	Please be reminded that each tender and contract are typical and being considered within its own scope.

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				cost calculation of the tenderer, can the percentages of requests realized in the previous procurement be shared?	
26	TS	11.7	In cases tests cannot be performed at a laboratory for a temporary period due to technical reasons, the Contractor should make an agreement with another laboratory/laboratories (other than the previously contracted subcontractor(s)) once approved by the Inspection and Acceptance Commission provided that test conclusion times and service flow are not disrupted. If the tests to be sent to an external laboratory are among those which cannot be run by the company at our laboratory on routine basis, conclusion times of the contracted external laboratory shall be applied. The laboratory/laboratories to be contracted by the Contractor should work with the current parameters using the same methods, run regular internal and external quality controls and be a member of an external quality control program for all current tests within the scope of work. It should also have a Biochemistry and Microbiology Laboratory License issued by the Ministry of Health. The Contractor is required to submit documents and agreements which demonstrate the required qualifications for this laboratory for approval of the Inspection and Acceptance Commission before starting the work. All tests to be run should be transferred to the LOS.	That the tests be carried out in another laboratory in the event of tests not being carried out in the laboratory temporarily due to technical reasons, but this laboratory is required to be a laboratory other than the contracted subcontractors under the contract. We think that the problem can be solved with an organization between contracted subcontractor laboratories; is there a special reason for requesting a different laboratory other than these laboratories?	Please see Corrigendum to TD

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27	TS	11.8	The Contractor should monthly report the number of tests run by the external laboratory/laboratories it commissioned to the Inspection and Acceptance Commission. The number of tests run by the external laboratory on a monthly basis shall not exceed 20% of the total number of tests for the respective month.	External Laboratories. However, we could not find the definition for the External Laboratory in the tender documents. Can an explanation be made for the external laboratory?	Please see Article 8.13 of the Annex II: Technical Specifications.
Appendixes					
28	App.1	…	…	There are discrepancies between the figures presented under the "Number of Migrant in the Province" column and the sum of the figures given under the "Number of Migrant in the District" column. We kindly ask the Contracting Authority to clarify the situation and provide guidance as to which of these figures should be taken into account in the Work Plan / O&M document.	The column named"Number of Migrant In The District", signify the number of migrants in the district having E/MHCs. The column named "Number of Migrant In The Province" signify number of all migrants in the province.
29	App.5	…	The contractor is issued a written warning by the Inspection and Acceptance Commission in the first event of failing to meet the following requirements set out in the Inspection, Control and Evaluation Form. The Contractor is imposed sanctions as per the penalty rate indicated below for each subsequent failure in relation to the same article.	It is stated in this section that a first written warning will be made by the Inspection and Acceptance Commission in case a requirement is not met for the first time, and in case of a subsequent failure on the same article, a penal sanction will be applied at the rate specified in the table. This article is interpreted by us as if an obligation is not fulfilled once and if it does not repeat, no penal sanction will be applied. Can you please confirm?	Please see Article 45 Penalties of Special Conditions and Annex II: Technical Specifications.