



European Tender Selection Guideline

Design, manufacture, delivery and assembly of various Hotcell lines for the micro-production of radioactive starting products and medical end products (GMP) based on Alpha and Beta Isotopes.

on behalf of

**Nuclear Research and consultancy Group
(NRG)**

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List of Definitions

For this Selection Guideline or any document which forms an intrinsic part of the Selection Guideline, the definitions set out in this list shall apply. All terms can be used either singular and plural.

Annex

An enclosure to the Tender Documents.

CET

Central European Time (UTC +1).

CEST

Central European Summer Time (UTC +2). NRG uses CEST during the Summer; between 1:00 UTC on the last Sunday of March and 1:00 UTC on the last Sunday of October.

Call for Quotation

The document that contains the invitation to Tender (to the Selected Candidates only), the applicable terms and conditions regarding to (second phase of) this Tendering Procedure, the technical specifications and performance conditions, contract conditions and other requirements of the project, service and/or the delivery wanted.

Candidate

The Supplier that submits a Qualification Application in this Tendering Procedure.

Consortium

A group of economic operators as referred to in Article 2.52 of the Dutch Public Procurement Act (Aanbestedingswet 2012).

Contracting Authority

Nuclear Research and consultancy Group (or abbreviation: NRG).

Days

Calendar days.

Directive

European public procurement Directive 2014/24 of 26 February 2014, on the co-ordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

Exclusion Grounds

Circumstances that are grounds for exclusion/disqualification of the Candidate and/or Tenderer.

Memorandum of Information

A document that contains the answers to all questions of Candidates/Tenderers, and (when applicable) changes to the Tender Documents.

PPA

Dutch Public Procurement Act (Aanbestedingswet 2012), applicable to this Tendering procedure.

Qualification Application

The application submitted by the Candidate in the phase 1 (pre-selection) of the Tendering Procedure.

Selection Criteria

Criteria to reduce the number of Candidates that the Contracting Authority will invite to Tender.

Selection Guideline

This document that contains the applicable terms and conditions regarding the Tendering Procedure, Exclusion Grounds, Suitability Requirements and Selection Criteria.

Standard Form

A form in a required layout that Candidate is obliged to use.

Suitability Requirements

The minimum requirements that the Candidates must meet.

Supplier

Any natural or legal person or public entity or group of such persons and/or bodies that offers on the market, respectively, products or services.

Tender

The detailed proposal submitted by the Tenderer in the second phase of this Tendering Procedure.

Tenderer

The Supplier that submits a Tender in (the second phase of) this Tendering Procedure.

Tender Documents

All documents in the Tendering Procedure (for this pre-selection phase i.a. the contract notice, Selection Guideline, Annexes and Memoranda of Information).

Tendering Procedure

This public procurement procedure following the restricted procedure.

UTC

Coordinated Universal Time.

1. Introduction

1.1 Nuclear Research and consultancy Group (NRG)

NRG is an internationally operating nuclear service provider. The company produces isotopes, conducts nuclear technological research, is a consultant on the safety and reliability of nuclear installations and provides services related to radiation protection. Research is performed for governments aimed at developing knowledge about nuclear technology.

NRG is a world market leader in the production of medical isotopes. In the Netherlands, NRG is the leading authority on integral radiation protection. NRG operates the High Flux Reactor owned by the European Union.

The company has around 600 world-class employees with high quality know-how and works for and with partners in healthcare, the energy market, industry, government and science

More information on NRG can be found on <http://www.nrg.eu/>.

1.2 Background information and scope

Nuclear medicine makes an essential contribution to the diagnosis and therapy of serious diseases, especially cancer. In recent years there have been many successful developments that ensure that nuclear medicine can make a specific demonstrable contribution to 'personalized medicine'. The need for these new nuclear therapies is expected to increase sharply as a result of the aging population, increased prosperity and the associated increase in old age diseases.

The availability of radioactive starting products and new nuclear drugs for clinical research and the nuclear infrastructure to make it is limited. Partly because clinical research is expensive and the market introduction of new nuclear drugs is a relatively long process. Researchers from university medical centers (UMCs) and companies urgently need an efficient nuclear infrastructure (one-stop-shop) to shorten the lead time for the development of new nuclear drugs.

In this context, a consortium of NRG, "Stichting Voorbereiding Pallas", four UMC's, and two other companies see it as an opportunity and as a social responsibility to accelerate the development of the new generation of nuclear medicines. "Petten" is unique due to the presence of all relevant links for the production of isotopes and radioactive starting products. The site also has a nuclear destination and offers sufficient room for expansion.

Within the project, the consortium is realizing a new state-of-the-art technical infrastructure that is suitable for small-scale production of radioactive starting materials and new nuclear medicines based on various isotopes, including alpha isotopes and beta isotopes. This infrastructure and the processes are (partly) certified according to the guidelines of Good Manufacturing Practices (GMP).

Hot-cell lines are part of this technical infrastructure. Three different lines are planned for the time being; a line for Alpha emitters, a line for Beta emitters in a GMP environment and a line for Alpha emitters in a GMP environment.

To realize these hot-cell lines, a Supplier is required, who can participate in the conceptual design and then carry out detailed engineering, manufacturing, delivery, and installation.

For the first line of hot cells to be supplied, this Tender is started to be able to select a Supplier based on functional specifications. In this Tender, potential Candidates will be requested to make an offer for the conceptual design, detail engineering, manufacturing, delivery and installation of the hot-cell line.

The starting point is that the party that is awarded the contract for the first hot-cell line also develops, delivers and installs the other two lines. Of course with a reservation whereby per line and per development stage, the NRG reserves the right to dissolve the agreement and to award the assignment to another party after testing the design and/or checking the pricing on market conformity.

The delivery of the first hot-cell line is planned for Q3 2020 and the other lines for the time being in Q4 2020.

1.3 Description of the contract

The Contracting Authority wishes to identify and select a Supplier who is capable of delivering the following products and services:

Three different lines are planned for the time being; a line for Alpha emitters, a line for Beta emitters in a GMP environment and a line for Alpha emitters in a GMP environment. The delivery of the first hot-cell line is planned for Q3 2020 and the other lines for the time being in Q4 2020.

The description of the products mentioned above and services is not exhaustive and NRG reserves the right to qualify/grant one or more of the products and services as optional and/or in a phased manner.

More detailed characteristics, quantities and specifications of the required/optional products and services will be provided to the selected Candidates during the second phase of this Tendering Procedure.

A (draft) agreement for the implementation of the contract will be enclosed in the second phase of this Tendering Procedure. To ensure that the contractor(s)/client(s) fulfill their obligations under according to the agreement, NRG reserves the right to demand additional financial security (such as – ‘default’ or ‘on demand’ bank guarantees). Especially when it comes to advance payments 100% financial security/coverage is required. More details will be provided to the selected Candidates during the second phase of this Tendering Procedure.

2. General Information Tendering Procedure

2.1 Public Procurement Act / Directive

The Dutch Public Procurement Act (Aanbestedingswet 2012), hereafter referred to as the PPA, applies to this Tendering Procedure.

The PPA entered into force on 1 July 2016, and provides a general legal framework for public procurement regulations and implements the European public procurement Directive 2014/24 of 26 February 2014, on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (hereafter referred to as the Directive).

2.2 Manner of tendering

This Tendering Procedure takes place following the restricted procedure, taking into account the complexity of the contract, the transaction costs and to secure the confidential nature of the information for both the Contracting Authority and the Tenderers.

The restricted procedure is divided into two phases.

Phase 1: (pre)selection phase

In this phase, NRG will select the five most qualified Candidates. This Selection Guideline describes how these five Candidates are selected (if less than five Candidates meet the minimum capacity levels, these Candidates will be selected).

Phase 2: quotation phase

After the qualified Candidates have been selected at the end of phase 1 (on condition that there are sufficient suitable Candidates), phase 2 (quotation phase) comes into effect: the selected Candidates are invited to Tender. To secure the confidential information the selected Candidates will receive the Call for Quotation after proper signing and enclosing the non-disclosure and confidentiality agreement (as provided with this Selection Guideline) to the Qualification Application (see paragraph 4.1.4). The Call for Quotation and the Tenders shall contain all the elements required and necessary for the performance of the project.

The Tenders may be clarified, specified and fine-tuned at the request of the NRG. However, such clarification, specification, fine-tuning or additional information may not involve changes to the basic features of the Tender or the Call for Quotation, variations in which are likely to distort competition or have a discriminatory effect.

NRG shall assess the Tenders received based on the award criteria laid down in the Call for Quotation and shall choose the most economically advantageous Tender from NRG.

At the request of NRG, the Tenderer identified as having submitted the most economically advantageous Tender may be asked to clarify aspects of the Tender or confirm commitments contained in the Tender provided this does not have the effect of modifying substantial aspects of the Tender or the Call for Quotation and does not risk distorting competition or causing discrimination.

2.3 Publication

The contract notice was published on www.Tenderned.nl and (via this site) in the supplement of the official publication journal of the European Union (TED).

The Contracting Authority has decided to make use of electronic instruments in this selection phase of the Tendering Procedure. This means that publication of Tender Documents, communications (submitting questions, the publication of the Memoranda of Information) will take place through a tendering website. This website can be reached at www.tenderned.nl.

2.4 Timeline for the restricted Tendering procedure

By publishing the contract notice this Tendering Procedure was started.

The following initial schedule has been drawn up for the Tendering Procedure:

Phase 1 – preselection phase	Starting date of the term	End date of the term	Time
Send publication of contract notice	7/5/2019		
Last day and time to submit questions	8/9/2019		9.00 a.m. CEST
Memorandum of Information is sent with the response to submitted questions	8/19/2019		
Last day and time to deliver Qualification Applications	9/25/2019		9.00 a.m. CEST
Assessment of Qualification Applications and selected Candidates are chosen	9/26/2019	9/30/2019	
The target date for a decision on preliminary selection and rejection of Candidates	9/30/2019		
The target date for definitive selection of Candidates after a period (7 calendar days) for lodging objections	10/6/2019		
Phase 2 – quotation phase	Starting date of the term	End date of the term	Time
The target date for sending the invitation to Tender	10/9/2019		
Last day and time to submit questions MOI 1	10/23/2019		9.00 a.m. CEST
Memorandum of Information is sent with the response to submitted questions	10/30/2019		
Last day and time to deliver Tender	11/20/2019		9.00 a.m. CEST
Assessment of Tenders and beneficiary contractor is chosen	11/21/2019	11/29/2019	
The target date for the decision on reporting intended award	11/29/2019		
The target date for the decision on reporting Definitive award after a period (20 calendar days) for lodging objections	12/1/2019	12/20/2019	

Table: Indicative timeline

NB: Tenderers shall be aware except of the dates which comply with mandatory timescales required by the Directive that all dates in this Selection Guideline are estimates only and the Contracting Authority reserves the right to alter the Tender timetable at its discretion. No rights may be inferred. Where any part of the procedure is subject to delay or postponement, this delay will be carried over to the remainder of the procedure.

2.5 Award of contract

- 2.5.1. The contract will eventually be awarded to the best Candidate. The award criteria, including their weighting, will be shared with the selected Candidates during the next phase of this Tendering Procedure.
- 2.5.2 The Contracting Authority expressly reserves the right not to award any contract proposed in the Tender Documents or to award only part or parts of the proposed product and or services.

3. Qualification procedure

3.1 Submitting of the Qualification Applications

Qualification Applications must have been submitted no later than **Wednesday, September 25, 2019 at 2.00 p.m.** through TenderNed.

Qualification Applications submitted after the deadline will be rejected. Submitting a Qualification Application in time is the full responsibility of the Candidate.

The Contracting Authority stresses that ensuring the correct submission of the Qualification Application is the responsibility of the Candidate. The correctness of the submission can be verified in two ways. First, the status of the response in the menu “Overzicht” [overview] will be changed into “Ingediend” [submitted]. Also, the Candidate will receive a message confirming the correct submission of its Qualification Application.

Since the Qualification Application must be submitted digitally through TenderNed in the manner described. Personal delivery of the Qualification Application and/or sending a hardcopy of the Qualification Application by regular mail is **not** possible and will not be accepted.

If there is a malfunction in TenderNed and the Candidate is, therefore, unable to submit his request to participate on time, before closing the safe, a procedure similar to that of Articles 2.109 and 2019a of the 2012 Procurement Act applies; to avoid disappointment it is advisable to start uploading your request to participate in the safe in good time and not to wait until just before the closing time of the safe.

To allow an efficient review process the Qualification Application should be built up as described in this Selection Guideline and as prescribed in **Standard Form A1 ‘Checklist’**, originally filled in and undersigned.

All parts of the Qualification Application must be signed by one member of the Candidates organization with the authority to commit to all information specified in the responses. For each tab, a separate file is requested.

3.2 Opening of Qualification Applications

After the final date of submitting the Qualification Applications, the Qualification Applications are opened and an official report is drawn up. The report will be sent to all the Candidates who have applied. Since the Qualification Applications will be opened digitally (by unlocking the information on the tender website TenderNed), Candidates cannot attend the opening.

3.3 Candidates

- 3.3.1 Candidates may only make a Qualification Application independently or in a form of cooperation with other contractors. The following types of Candidates can be distinguished:
- Independent Candidate;
 - Candidate is a primary contractor;
 - Groups of economic operators as Candidate (Consortium).

- 3.3.2 Only one legal entity per group of companies may submit a Qualification Application as Candidate. However, several legal entities from a group may report as a single Candidate in the form of a group of economic operators (Consortium). A group of economic Operators is understood to mean: a legal entity together with its subsidiaries in the sense of article 24a and 24b, Book 2 of the Dutch Civil Code.
- 3.3.3 If a Qualification Application is submitted in violation of paragraph 3.3.2, only the Qualification Application of the Candidate that was delivered first will be considered.
- 3.3.4 By submitting a Qualification Application independently, a Candidate purports that can carry out the contract entirely independently (without having to make use of the services of third parties). The Candidate must satisfy all the imposed requirements (*i.a. Exclusion Grounds, Suitability Requirements and Selection Criteria*) and produce the information requested.
- 3.3.5 In the event a Qualification Application is submitted by a Candidate who will act as the primary contractor, who can independently satisfy the imposed requirements (*i.a. Exclusion Grounds, Suitability Requirements and Selection Criteria*), the same requirements apply as for an independent Candidate as referred to in paragraph 3.3.4.
- 3.3.6 If the primary contractor can only satisfy the imposed requirements (*i.a. Suitability Requirements and Selection Criteria*) by engaging subcontractors, he must submit the relevant paragraphs in the **Standard Form A2** (UEA).
- 3.3.7 It is not permitted to submit more than one Qualification Application.
- 3.3.8 No changes in the composition of a Candidate will be accepted after the closing time for Qualification applications. The composition of the Consortium that has submitted a Qualification application may no longer be altered in the continuation of the Tendering Procedure (phase 2).

3.4 Content(s) of the Qualification Application

- 3.4.1 The Candidate must base the Qualification Application on this Selection Guideline including all Annexes and any information provided in Memoranda of Information. In the case a Candidate does not add or completely enclose the information exactly as requested then this can (if not repaired on time when repairing is permitted) lead to disqualification, for this Tendering Procedure. This also applies when the Candidate alter the information given by the Contracting Authority in Annexes and forms added to this Selection Guideline.
- 3.4.2 If the Candidate wishes to elucidate particular questions using documents, clear reference must be made to the pages of the relevant document.
- 3.4.3 The Qualification Application must be in the English language.
- 3.4.4 All prices must be quoted in EUR, excluding VAT.
- 3.4.5 Qualification Applications that do not satisfy the requirements as put forth in these Selection Guide, the publication of contract notice, the Tendering Procedure, or the Memoranda of Information may be disqualified.

3.5 Applicable conditions

By submitting a Qualification Application, the Candidate approves and accepts all terms and conditions stated in this Selection Guideline. Annexes and Memoranda of information are an integral part of this Selection Guideline.

All information as given in this Selection Guideline is in the best capable means. Contracting Authority declines all liability for the correctness and completeness of the given information. Candidates are considered to investigate all relevant conditions concerning this Selection Guideline including using submitting requests for clarification.

The Candidate is required to clarify the content of its Qualification Application and/or participate actively and openly during verification meetings with the Contracting Authority at the request of the Contracting Authority.

3.6 Adjustment of Tender Documents

The Contracting Authority reserves the right at its sole discretion to complete or adjust the Tender Documents, in case new developments make this necessary. These adjustments will be communicated in writing to all Candidates in one or more Memoranda of Information. In situations that are not foreseen in the Tender Documents, the Contracting Authority is to decide.

3.7 Prorogation of Tendering Procedure

The Contracting Authority reserves the right at its sole discretion to discontinue the Tendering Procedure at any time and makes no commitments or otherwise, that this Selection Guideline and/or other Tender Documents process will result in a business transaction with one or more parties.

3.8 Intellectual property rights

Unless otherwise indicated, by participating in this Tendering Procedure intellectual property rights do not pass on from the Tenderer to the Contracting Authority.

3.9 Exchange of Information

- 3.9.1 During the Tendering Procedure, NRG will guarantee equal treatment of all Candidates and Tenderers. NRG will not provide information that gives one or more Candidates and Tenderers an advantage over others. All communication related to the Selection Phase takes place via TenderNed, or via the Contact person in case TenderNed is not functioning properly. Communication with the Contact person will be by e-mail only and from/to a single person within the Candidate's entity.

Contact person

Mr. M. Scheffer

email: scheffer@nrg.eu (only in case TenderNed is not functioning properly).

It is prohibited to contact any other NRG's employee in connection with the Tendering Procedure. Non-compliance with this provision shall in principle lead to exclusion from the Tendering Procedure.

- 3.9.2 The Candidate has the opportunity to submit written questions about the Tendering Procedure and the Selection Guideline. Questions must be submitted through TenderNed. When asking questions you should refer as specifically as possible to the relevant tender Document.
- 3.9.3 A Memorandum of Information will be drawn up containing the anonymized questions and its answers by or on behalf of the Contracting Authority, to the extent that this Memorandum serves to supplement, amend or clarify the Qualification Procedure. The last Memorandum of Information will be published through TenderNed at the latest six Days before the Qualification Application term expires. The Contracting Authority is not bound by any oral announcements, promises or agreements that are not set down in a Memorandum of Information. As soon as any additional information is published, automatic notification e-mails will be sent to all persons who have registered at TenderNed for this Tendering Procedure by clicking on *the keep me informed button "houd mij op de hoogte van deze aanbesteding"* (as shown below) in TenderNed.



Candidates are responsible for their correct registration at TenderNed.

From the date on which the assignment is announced, Candidates must check the internet page mentioned above regularly to see if any Forms or appendices have been added, since notification messages may not be received in case of possible erroneous entries, or for other reasons.

- 3.9.4 The Tender Documents concerning this Selection Guideline become final after publishing the final Memorandum of Information through TenderNed. The Contracting Authority therefore advises Candidates not to submit a Qualification Application before the publication of the final Memorandum of Information. All Memoranda of Information form an intrinsic part of this Selection Guideline. The content of the Memoranda of Information prevails above the original Selection Guideline, whereas a Memorandum of Information of a more recent date prevails above a Memorandum of Information of an earlier date.

3.10 Lack of clarity and additional information

- 3.10.1 The Contracting Authority keeps the right to ask additional information in case of clear misunderstanding or lack of clarity. This additional information forms an inextricable part of the Qualification Application. If the Candidate doesn't deliver the information asked, or if he delivers the information too late, his Qualification Application will be laid aside.

4. Criteria for qualitative selection

4.1 General

- 4.1.1 The criteria described in chapters 4, 5 and 6 will be maintained during this Tendering Procedure. To assess whether the Candidate satisfies the Selection Criteria, the Candidate must submit the information mentioned in these chapters. In the event the Candidate fails to produce the information as mentioned earlier in its Qualification Application, the Contracting Authority reserves the right to disregard the Qualification Application.
- 4.1.2 In addition to the Exclusion Grounds, Suitability Requirements and Selection Criteria mentioned in the following articles, Candidates must also declare agreement with the contents of the Qualification Procedure and Memoranda of Information by submitting a Declaration of no objection as **Standard Form A5: Declaration of no objection**. If a Candidate fails to declare its full agreement, the Contracting Authority reserves the right to disregard the relevant Qualification Application.
- 4.1.3 All information provided by or on behalf of the Contracting Authority during the Tendering Procedure that is not published by the Contracting Authority in the public domain, must remain strictly confidential and may only be shown to co-workers who need the information for the application. Neither may the Candidate/Tenderer in any way disclose any information provided by the Contracting Authority within the framework of the Tender to third parties. This confidentiality must also be maintained if the Tenderer is not selected. Furthermore, the information submitted by Candidate/Tenderer to the Contracting Authority shall be treated as strictly confidential by or on behalf of the Contracting Authority, except the legal obligation of publication.
- 4.1.4 In order to receive the information and invitation to Tender, the Candidates (and/or - if applicable - each participant in the Consortium and/or - if applicable - each subcontractor as referred to in paragraph 3.3.6), must complete and sign the Non- disclosure and confidentiality agreement as **Standard Form A4: Non-disclosure and confidentiality agreement** with the Qualification Application. If a Candidate is selected and invited to the 2nd phase of this Tendering Procedure, the NDA will be signed by NRG and it will be returned to the selected Candidate.
- 4.1.5 For the selection of Candidates it is necessary that all statements and descriptions mentioned in the Tendering regulations are included in the Qualification Application. The failure to satisfy the minimum requirements of the Selection Criteria may result in exclusion from further participation in the Tender Procedure.

5. Exclusion criteria

5.1 Grounds for exclusion from participation

The grounds for exclusion are meant to exclude non-integrity companies and, based on the suitability requirements, it is assessed whether a Candidate is suitable to perform the contract. This chapter describes the requirements and criteria that your company must meet, whether or not in collaboration with others, to be eligible for the award and what information you must provide for this when you register.

Uniform European Tender Document (UEA) NRG assesses the application of the Exclusion Grounds as stated on the UEA under part III A and B (mandatory Exclusion Grounds) and/or part III under C (relevant optional Exclusion Grounds for this specific assignment).

The UEA is included in Appendix A2. The Candidate must upload the UEA correctly, completely, truthfully and legally signed, via TenderNed, Questionnaire tab. If a ground for exclusion applies to the Candidate, the Candidate must state the information requested in the UEA.

Uniform European Tender Document (UEA)

The NRG assesses the application of the Exclusion Grounds as stated on the UEA under part III A and B (mandatory Exclusion Grounds) and / or part III under C (relevant optional Exclusion Grounds for this specific assignment), the Suitability Requirements in Part IV and the Selection Criteria as stated in Part V and in section 4.2 of this Tender Document. The UEA is included as Appendix 1.

The Candidate must upload the UEA correctly, completely, truthfully and legally signed, via Commerce Hub, Questionnaire tab.

If a ground for exclusion applies to the Candidate, the Candidate must state the information requested in the UEA.

Explanation of the UEA:

Part I UEA: will be filled in by NRG.

Part II UEA: this part is for the Candidate. If the Candidate relies on the capacity of other companies to meet the Suitability Requirements, he must complete part IIC. Each company on which the Tenderer relies on the capacity of this company must then separately enter a UEA and follow the instructions for further completion of the UEA.

If a Candidate is registering with a main / subcontractor structure, he is required to enter the names of his subcontractors in Part IID.

Part III UEA: The NRG has specified which Exclusion Grounds apply.

Part IV UEA: The NRG sets out below what Suitability Requirements it requests. Candidate indicates in the UEA whether or not he satisfies.

Part V UEA: The NRG sets out below which Selection Criteria it asks to reduce the number of candidates to five. The Candidate indicates in the UEA whether or not he satisfies and how he complies.

Part VI UEA: The Candidate must sign the UEA by a person authorized to represent the company or persons appearing from the Trade Register of the Chamber of Commerce. If it appears from the Chamber of Commerce extract that someone has limited authority to represent, (additional) evidence must be submitted that the signatory's authority to act is sufficient for the relevant registration.

If the Candidate uses a digital signature, this must be objectively verifiable for the NRG in a simple manner. If you do not use a digital signature, you must enter a "wet signature" and scan and upload the UEA.

Grounds for exclusion

In Part III UEA, the Candidate indicates whether or not he satisfies and answers the stipulations ask / provide the requested information.

6. Suitability Requirements

6.1 General

- 6.1.1 Candidates must at least meet the minimum requirements as set from now on. Candidates not meeting one or more of these minimum requirements will be excluded from this Tendering Procedure.
- 6.1.2 At the Contracting Authority's request, the Candidate must provide additional information or explanation on the statements and documents he has provided.

6.2 Suitability to pursue the professional activity

In Part IV UEA, the Candidate indicates whether or not he meets the following suitability Requirements.

Financial and economic capacity

The NRG sets the following requirements with the accompanying supporting documents:

- If the Candidate has indicated in part IIC UEA that he is using the financial capacity of another company, the Contracting Authority requires that both the Candidate himself and the entrepreneur whose capacity is used are jointly and severally liable for the execution of the assignment (in accordance with Article 2.92, paragraph 3 of the Aw 2012).
- The NRG would like to know whether (the winning) Candidate is part of a holding or Parent company and if so whether the financial (annual) figures of the holding are used. As evidence, the parties who proceed to the award phase submit the completed Appendix 2 from this Tender Document;
- The Candidate must be appropriately insured, ie he has business liability insurance whose coverage must be at least € 5.000,000 (in words: five million euros) per event and a maximum of € 10.000.000 (in words: ten million euros) on an annual basis.
- As evidence, the parties who proceed to the award phase submit a copy of a business liability insurance policy or an insurance certificate or equivalent.

6.3 Technical and/or professional ability

- 6.3.1 To be eligible for the contract, the Candidate must satisfy the minimum requirements for Technical and/or professional ability necessary for carrying out the contract. Therefore the Candidate must demonstrate that it possesses each of the following core competencies.

The Candidate is asked to describe one reference project for the following core Competencies over the past seven years. The completed reference project must have been delivered within a period of seven years, counted from the deadline for submission of this Tender Procedure. By submitting the reference(s), the Candidate demonstrates that he has sufficient expertise and experience to perform the requested services. The reference must be described in such a way that it is clearly visible to the NRG that the core competence(s) has already been performed by the Contractor. The reference(s) to be submitted must clearly and unambiguously show the experience as requested by the Contracting Authority.

The reference(s) must furthermore be provided with a statement of satisfaction on behalf of the commissioning organization, not being the organization of the Candidate, from which at least it follows that the client is satisfied with the performance of the work by the Candidate. Candidates are allowed to meet several core competencies with one (1) reference, provided that the statement clearly and unambiguously shows which core competencies are involved. It is not possible to meet one (1) by combining or bundling multiple references core competence.

Each reference form (**Standard Form A3**) must be verifiable. The Standard Form must contain a description of the nature of the work and the execution period of the assignment. In addition, it must provide a reference name and address details, such as company name, address, e-mail and phone number of the contact person at the reference entity. If a reference cannot be verified, the Contracting Authority may decide not to admit it.

6.3.2 The core competencies required by NRG are:

1. Experience with basic design, detailed engineering, manufacture, delivery and installation of a Hot cell line of at least 2 coupled cells for Medical Isotopes with a Beta characteristic;
2. Experience with Basic design, detailed engineering, manufacture, delivery and installation of an EU cGMP grade A Hot cell line of at least 2 coupled cells for Medical Isotopes with a Beta characteristic;
3. Experience with Basic design, detailed engineering, manufacture, delivery and installation of a Hot cell line of at least 2 coupled cells for Alfa emitters.

6.3.3 This must be proved by providing references. References must meet the following (minimum) requirements.

Ad 1 The Candidate must provide one (1) reference (by submitting a fully completed **Standard Form A3**), which adequately demonstrates that the Candidate has experience with the asked references.

6.3.4 Each reference includes a description of how a core competency is provided or produced (facts and figures), contact details, and can be accompanied by a declaration on customer satisfaction (*see chapter 8*). Each core competence must be addressed in the references, although one reference may cover one or more core competences. In case one reference covers more than one core competency the Candidate is obliged to explicitly refer to the core competences the reference is substantiating. It is not allowed to submit more than one reference for a specific core competency.

6.3.5 In one reference document, the Candidate must provide a description of the years of experience the company has within that specific core competence and must elaborate on the approach and lessons learned during these years (*see chapter 8*).

6.3.6 The Contracting Authority reserves the right to check whether a reference/references meet all requirements mentioned above without informing the Candidate in advance. The Candidate must have informed the contact person of the possibility that he/she may be contacted by the Contracting Authority before submitting the Qualification Application. If the Candidate did not prove that it meets the aforementioned minimum requirements in the field of technical skills, the Qualification Application will be dismissed and the Candidate is no longer eligible for further assessment, substantive or otherwise.

The Candidate must also indicate the capacity in which he has carried out the work: as the main contractor, Consortium or subcontractor. If registration is made as a partnership (combination) or with third parties (subcontractors), the relevant combinator (s) and / or subcontractor (s) for the part of the assignment for which they are deployed must show that they have the core competence to perform this part properly.

For combinations, the following applies to the experience requirement:

- Each combinator must meet at least 50% of the required experience requirement individually;
- for a combination of two or more companies, at least 100% of the required experience requirement must be met jointly.

The reference must meet the following minimum requirements:

- The reference contains a description of the reference in such a way that the NRG can easily determine that the requested core competence is met;
- the assignment / project mentioned in the reference must have been completed or at least be in progress.

The reference provided by the Candidate can be checked by the NRG. The NRG wishes to be able to contact the contact person named directly (without the intervention of the Candidate). The NRG expects the Candidate to arrange this with the relevant organization and contact person. The above-mentioned core competencies serve as knock-out criteria. Candidates who do not meet this requirement will be excluded from further participation.

6.4 Quality assurance

The NRG requests supporting documents (see below) from the Candidate who is eligible for award of the contract. The winning Candidate (and combinations or companies whose capacity he relies on) is asked to submit the supporting documents by request within seven Days.

This concerns the following supporting documents:

- Extract from the Trade Register of the Chamber of Commerce, which is not older than six months on the date of submission of the application.
- A Declaration of Conduct for Procurement from the Ministry of Justice and Security, not older than two years from the registration deadline.
- A statement from the Tax Authorities regarding compliance with taxes and social security contributions, not older than 6 months from the deadline for registration.
- Copy of business / professional liability insurance policy or insurance certificate or equivalent;
- The most recent auditor's report or, where appropriate, the assessment or composition report does not contain a so-called continuity paragraph. Proof: the proof is a financial statement of the most recent financial year approved by a chartered accountant (or equivalent person in office) or a separate statement by a chartered accountant.
- ISO 9001
- In possession of a VCA/SSC certification or demonstrably equivalent for the assembly & service work.

For companies established outside the Netherlands, equivalent supporting documents issued by the official authorities in that country apply.

7. Assessment procedure

7.1 Procedure for assessing Qualification Applications

The assessment procedure begins after the deadline for the Candidates to submit Qualification Applications. The assessment procedure will take place as follows:

- **Step 1 Check for completeness of the Qualification Application**
The Contracting Authority checks whether the Qualification Application submitted is complete. The Contracting Authority reserves the right to ask clarification questions about the Qualification Applications received. Candidates must answer these questions within seven Days. Failure to satisfy these conditions can result in the Qualification Application not being further processed.
- **Step 2 Assessment for minimum requirements of the Qualification Application**
The Contracting Authority checks whether a Candidate satisfies all the criteria (Exclusion Grounds and Suitability Requirements) included in chapters 5 and 6 of the Selection Guideline. A Candidate who does not satisfy one or more of the minimum requirements is excluded.
- **Step 3 Evaluation of the Selection Criteria**
In case there are more than five Candidates who satisfy the minimum requirements a selection will be made from suitable Candidates. After evaluation of the Selection Criteria according to chapter 8, no more than five (5) Candidates will be invited to participate in phase 2 of this Tendering Procedure.

8. Selection Criteria and regulations

8.1 General

In case there are more than five Candidates who satisfy the minimum requirements a selection will be made from suitable Candidates.

Only Candidates that meet all Suitability Requirements and to whom no Exclusion Grounds apply will be assessed based on the Selection Criteria defined below. The Selection Criteria and their corresponding weights are as follows:

8.2 Selection Criteria

Experience with basic design, detailed engineering, manufacture, delivery and installation of an EU cGMP grade A Hot cell line of at least 2 coupled cells for Medical Isotopes with an alpha characteristic

Rating	points
More than five years ago	0 points
Within five years	15 points
Within three years	20 points

Selection of five Candidates

Selection of five Candidates takes place by assessing the Selection Criteria. The five Candidates who achieve the highest total score will be invited to submit a Tender during the award phase. The total score is calculated by adding together the scores on the various Selection Criteria. If the Candidates number 5 and number 6 (7, 8, etc.) in the ranking have achieved the same total score, the lot will determine by means of a lottery which Candidate will be admitted as Candidate number 5 to the award phase.

8.3 Invitation to Tender

- 8.3.1 Following the evaluation of the reference projects, the five (5) best scoring Candidates will be invited to participate in Phase 2. The Contracting authority will inform each Candidate simultaneously of the selection decision using a notification, stating the reasons for the selection decision.
- 8.3.2 If within a period of ten Days an unsuccessful Candidate has started proceedings for an interim injunction with the competent interim injunction judge, which should be evidenced by sending a copy of the writ of summons (see paragraph 9.6.2), the invitation to Tender will, in principle, not be sent until judgment has been passed. If an interim procedure is pending, the Candidates will be informed thereof at the earliest opportunity.
- 8.3.3 If the Contracting Authority itself has discovered any errors in the Tendering Procedure, or believes that a complaint submitted by a Candidate should be considered founded without waiting for the outcome of any injunction proceedings, the Contracting Authority may decide to revoke the selection decision.

- 8.3.4 In the circumstance that more than five (5) Candidates fulfill the minimum requirements and two or more Candidates eligible for selection obtain equal scores on their references, the equal scoring Candidates will be selected by lottery. Such a procedure will be supervised by a notary public or solicitor.

9. Final Provisions

9.1 Applicability of the regulations

- 9.1.1 Each Candidate is considered to be familiar with these Tender regulations and to have agreed to its applicability by submitting the Qualification Application.
- 9.1.2 The publication of contract notice, the Qualification Procedure, its Annexes and the one or more Memoranda of Information are an integral part of this Qualification Procedure.

9.2 General declaration from the Contracting Authority

- 9.2.1 Candidates must base their Qualification Applications on the information provided by the Contracting Authority in the Qualification Procedure, the Memoranda of Information or other relevant documents distributed by or on behalf of the Contracting Authority.
- 9.2.2 The information, particularly the management information, as it has been provided to the Contracting Authority, is provided to the Candidates to the Contracting Authority's best knowledge in the specifications and Memoranda of Information or otherwise. The Contracting Authority cannot guarantee that there are no inaccuracies in the aforementioned information. The Contracting Authority cannot be held liable for the contents of the aforementioned information.

9.3 Variation

- 9.3.1 No variation deviating from the requirements in the Qualification Procedure is permitted.

9.4 Costs incurred

No costs incurred by a Candidate in connection with participation in the Tendering Procedure will be reimbursed. The Contracting Authority cannot be held liable by a Candidate for costs and/or other expenses, incurred or to be incurred by a Candidate in relation to the Qualification Application, nor during the Qualification Application period, nor during any meetings, regardless of whether these meetings lead to the awarding of a contract to the Candidate or not.

9.5 Tender conditions

- 9.5.1 By submitting a Qualification Application, the Candidate fully accepts and agrees to comply with the terms and conditions below for participation in the procedure prior to the Qualification Application until after the definitive awarding and subject to what is indicated below.
- 9.5.2 General restrictions:
 - The Contracting Authority cannot be required to award the contract, options or parts of the contract.

- The Contracting Authority is not required to reveal its internal documents, such as the results of evaluations and recommendations regarding the Qualification and the selection of Candidates.
- The Contracting Authority reserves the right to temporarily suspend or definitively terminate the Tender Procedure at any time. Candidates cannot claim compensation of any costs incurred in the context of the Tender Procedure in such a case.
- The Contracting Authority reserves the right to amend the preconditions for the Tender during the Tender Procedure when new insights or developments give cause for this. In the aforementioned circumstance Candidates will be given the opportunity to submit a new Qualification Application based on the new preconditions. In such cases however, Candidates cannot claim compensation for any costs incurred in the context of the Tender Procedure.
- A Qualification Application that does not satisfy the requirements of the Qualification Procedure is invalid. In addition, also invalid is a Qualification Application to which one or more conditions are attached.
- Once a Qualification Application is submitted it must be irrevocable. A Qualification Application that is not irrevocable is invalid.

9.6 Settlement of disputes

- 9.6.1 Dutch law applies to any disputes regarding the Tender Procedure and the civil court in the district of North Holland is competent to settle such disputes.
- 9.6.2 If a non-selected or rejected Candidate thinks that NRG's decision violates the law or any other applicable legal regulations, he must correctly summon NRG within the term of ten Days after the dispatch of the afore-mentioned decision. If the Candidate does not summon NRG within the said period in the correct manner, NRG will conclude that no legal action will be taken. Any legal actions against NRG shall not suspend the Tendering Procedure.