

## **MINUTES - Type of contract – Services**

### **FOR THE ARGUMENTATION AND APPROVAL OF TECHNICAL SPECIFICATIONS AND QUALIFICATION CRITERIA**

**OBJECT OF THE PROCEDURE:** “Evacuation, Treatment and Disposal of Hazardous Hospital Waste at S.U.O.G.J. Mbretëresha Geraldine Tirana.

**RELEVANT CODE IN THE COMMON PROCUREMENT VOCABULARY (CPV)** Collection, transport and disposal of hospital waste - 90521100-6 Collection, transport and disposal of hospital waste

Limited fund of the procedure: 18,300,000 (eighteen million three hundred thousand) lekë, excluding VAT, or 186,468.31 (one hundred eighty-six thousand four hundred sixty-eight points thirty-one) euros excluding VAT.

*Referring to the exchange rate of the Bank of Albania dated 27.05.2025 (98.14 lek/euro).*

Based on article 21, point 2, of Law no. 162/2020 "On public procurement", article 2, point 2/c and article 78, point 2, of VKM no. 285, dated 19.05.2021 "On the approval of public procurement rules", and in accordance with the specific legislation for the procurement object, as follows:

- Law No. 10463, dated 22.09.2011, “On Integrated Waste Management”, as amended;
- Law No. 10431, dated 09.06.2011, “On Environmental Protection”, as amended,
- Council Decision No. 798, dated 29.09.2010, “On the approval of the regulation “On the management of hospital waste”;
- Council Decision No. 229, dated 23.04.2014, “On the approval of the rules for the transfer of non-hazardous waste and the information that must be included in the transfer document”;
- Council Decision No. 371, dated 11.06.2014, “On the approval of the rules for the delivery of hazardous waste and the document of their delivery”;
- Council Decision No. 402, dated 30.06.2021, “On the approval of the waste catalog”;
- Order No. 135, dated 16.4.2015 “On "approval of the method of administering the format of the individual transfer register and the national transfer register, as well as the method of administering them"

the contracting authority/entity Central Purchasing Body "**Concentrated Purchases Operator**" has drawn up the minutes for the argumentation and approval of the specifications technical and qualification criteria for the aforementioned procedure.

The bidder must present:

## **2. SPECIAL QUALIFICATION CRITERIA**

1. Bidder shall submit:

a. *Summary Self – Declaration form, as per Appendix 10*

b. *Bid insurance, as per Annex 3;*

2. Bidder shall submit:

### **2.1 Professional Capacity of Economic Operators:**

2.1.1 For treatment methods and technologies defined in Law No. 10448, dated 14.07.2011 “On environmental permits”, in the Council of Ministers No. 798, dated 29.9.2010 “On the approval of the

regulation for the administration of hospital waste” and in the Terms of Reference of the DST (except incineration), or equivalent technology, the Economic Operator must have and submit:

**1.a** Environmental permit of type A (with code III.1.C) or type B (with code III.1.B) together with the relevant Approval Act,  
And

**1.b** The relevant license of category III.2.B (For the treatment of hazardous hospital waste) which includes the hazardous waste codes as follows:

- **18 01 01** - Scalpels, syringes, sharp instruments (except 18 01 03);
- **18 01 03** - Waste, the collection and disposal of which requires special treatment to prevent infections;

**2.1.2** For the method and technology of treatment BY INCINERATION, the Economic Operator must have and submit:

**2.a** Environmental Permit of type A (with code III.1.C) together with the relevant Approval Act and

**2.b** The relevant License of category III.2.B (For the treatment of hazardous hospital waste) which includes the following hazardous waste codes:

- 18 01 02 - Body parts and organs, including blood bags and blood preservatives and blood reserves (except 18 01 03);

**Reasoning:** The above request is based on Article 77, points 1/a and 2, of the LPP, Article 41, point 4/a, of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of public procurement rules", as amended, and in support of point 5 Waste Management of Annex 1 Environmental permits of types A, B and C depending on the production capacity limit of Law No. 10448, dated 14.07.2011 "On environmental permits", as amended, Law No. 10431 dated 09.06.2011 "On environmental protection", Council of Ministers No. 798, dated 29.09.2010 "On the approval of the regulation, On the administration of hospital waste", Council of Ministers No. 402, dated 30.06.2021, "On the approval of the waste catalog", the National Guide "On the Management of Hazardous Hospital Waste" and according to the definitions made in the National Guide "Safe Management of Hospital Waste", Law No. 10081, dated 23.02.2009 "On licenses, authorizations and permits in the Republic of Albania", as amended, Law No. 10463, dated 22.09.2011 "On integrated waste management", as amended and VKM No. 538 dated 26.05.2009 "On licenses and permits, handled by/or through the Central Waste Management Centre and some other joint sub-legal regulations", as amended.

**2.1.3** The economic operator must submit the respective Hygienic and Sanitary Approval Act for the facilities where it carries out the activity of treating hospital waste, issued by the ISHSH (State Health Inspectorate).

**Reasoning:** This criterion is based on the requirements of Article 10 of Law No. 7643 dated 12.12.1992 "On Sanitary Inspection", as amended, and Article 10.3 of Chapter IV "Environmental Permit and Hygienic-Sanitary Approval Act" of the Council of Ministers No. 798, dated 29.09.2010 "On the approval of the regulation on the administration of hospital waste", which provides: "10.3. The State Sanitary Inspectorate, after the hygienic-health expertise, issues a hygienic-sanitary approval act for the exercise of the activity".

**2.1.4 The economic operator must submit:**

- a. Certificate that the operator has paid the annual fee for the Environmental Permit, to the National Environment Agency, in accordance with the Council of Ministers No. 417, dated 25.06.2014, "On the Approval of Environmental Permit Fees".

- b. Certificate that the operator has no administrative measures in force from the inspection structures of the National Environment Agency, in accordance with Law No. 10433 dated 16.06.2011 “On Inspection in the Republic of Albania”, Law “On Environmental Permits” No. 10448 dated 14.07.2011 and LAW No. 10463, dated 22.9.2011 “On Integrated Waste Management”.

**Reasoning:** These requirements are established on the basis of Article 41, point 6, of the Decision of the Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended, which allows the Contracting Authority/entity, in addition to the requirements provided for in this article, to determine other specific criteria, depending on the object being procured, which it deems necessary for the successful execution of the contract. The requirement for the submission of the above-mentioned certificates ensures that the CA economic operator carries out its activity, related to the object of procurement, in accordance with the legal provisions.

## **2.2 Economic and financial capacity:**

2.2.1 To prove financial and economic capacity, economic operators must submit proof of annual turnover for the last 3 (three) financial years (2022-2023-2024), where the turnover value for at least one of the years of the required period must be no less than the value of limit fund.

The above requirement is considered fulfilled if economic operators reach the minimum turnover value, in at least one year of the required period.

**Reasoning:** The above requirement has been determined based on the value of the limit fund of this procedure, as well as based on Article 77, point 3, of the LPP, as well as Article 43, of the Council of Ministers No. 285, dated 19.05.2021 “On the approval of public procurement rules”, as amended.

The criterion of point 2.2.1 has been established referring to Article 43, point 2/a of the Council of Ministers No. 285, dated 19.05.2021 “On the approval of public procurement rules”, as amended, where the required value for the minimum annual turnover is clearly defined, and point 3 of Article 77 of Law No. 162, dated 23.12.2020 “On public procurement”, as amended, as well as the Recommendation of the Public Procurement Agency No. 7998 dated 24.12.2021. The required value is within the limits set in the provisions above, it has been set in order to ensure competition and participation of economic operators in this procurement procedure, as well as to ensure the economic and financial potential of the bidding EO, which is directly related to the sustainability and continuity of the activity of economic operators in the market, as an important element in the realization of the procurement object and the fulfillment of contractual obligations. The determination of the years required for the submission of the annual turnover certificate has been made by referring to the legislation in the field, specifically, Article 43, point 1, of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of public procurement rules", as amended. In setting this criterion, the CA has taken into account Article 61 of Law No. 29/2023 "On income tax" as well as the requirements of Law No. 25/2018 “On accounting and financial statements”.

**2.2.2.** Economic operators must submit annual balance sheets for the financial years (2022, 2023, 2024), accompanied by the Expertise Act of the Authorized Accountant, only in the case when they are in accordance with the provisions of Article 41 of Law No. 10091 dated 05.03.2009 “On statutory audit, organization of the profession of registered accountant and approved accountant”, as amended.

The criterion is considered fulfilled if in two consecutive balance sheets there is no negative ratio between assets and liabilities.

**Reasoning:** The criterion is established based on Article 77, point 3, of the LPP; Article 43, point 4, of the Council of Ministers No. 285, dated 19.05.2021 “On the approval of public procurement

rules”, as amended, as well as Article 41 of Law No. 10091, dated 05.03.2009 “On statutory audit, organization of the profession of registered accountant and approved accountant”, as amended.

The determination of the years required for the presentation of balance sheets is made by referring to the legislation in the field, specifically, in Law No. 9920 dated 19.05.2008 “On Tax Procedures in the Republic of Albania”, as amended, and the sub-legal acts implementing it.

The economic and financial criterion serves the contracting authority to create certainty that economic operators have the financial capacity to implement the framework agreement.

## **2.3 Technical capacity:**

2.3.1 The economic operator must submit evidence of previous similar services, performed during the last three years from the date of publication of the contract notice, in a value not less than 40% of the value of limit fund.

To prove previous similar experience, economic operators must submit the following evidence:

- a) for previous experience realized with the public sector, the economic operator must submit certificates issued by a public entity for the successful fulfillment of the contract, indicating the value, the deadline for the completion of the contract, or/and tax sales invoices, completed in accordance with the requirements of the legislation in force, and declared to the tax authorities, indicating the dates, amounts and services performed.
- b) for previous experience with the private sector, the economic operator must submit sales tax invoices, completed according to the requirements of the legislation in force, and declared to the tax authorities, indicating the dates, amounts and services provided.

**Reasoning:** The above requirement is determined based on Article 77 of Law No. 162, dated 23.12.2020 "On Public Procurement", as amended, and Article 41, point 3 of the Council of Ministers No. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", as amended. This criterion requires economic operators to prove that they have the necessary experience to implement the contract, therefore it is required that previous similar services be in the value of no less than 40% of the value of the limit fund, which is within the limit value determined in the above-mentioned provisions.

The determination of the required value for similar contracts is argued as follows:

The required value is determined based on the legislation in the field, specifically, Article 41, point 3 of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of the Public Procurement Rules", as amended, thus serving as a guarantee for the CA that the bidders possess the capacity and experience to successfully implement the contract, according to an appropriate quality standard and in compliance with the technical specifications.

2.3.2 The operator must have at least 2 vehicles that transport hospital waste, according to the technical specifications and terms of reference of the service subject to procurement.

To prove the fulfillment of this criterion, the economic operator must have and submit the following supporting documents:

-documentation for the vehicle owned, rented, or loaned (purchase invoice / customs clearance documents / rental contract / loan-use contract / donation contract / any other document by which the right of ownership or use is acquired according to the Civil Code of the Republic of Albania).

-Vehicle registration certificate, Test certificate, Compulsory motor vehicle insurance policy for vehicles together with the Hygienic and Sanitary Approvals, Photos of the vehicles where the license plate and relevant signage are clearly visible.

*This criterion is considered fulfilled by completing the form according to Annex 10 of the DT. The supporting documents required above shall be submitted by the first qualified bidder, prior to the*

*publication of the award notice and the start of the appeal deadlines or if clarifications are requested by the Contracting Authority.*

**Reasoning:** This criterion is established in accordance with point 4 of Article 77 of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, and point 4/ç of Article 41 of the Council of Ministers No. 285, dated 19.05.2021 “On the Approval of the Public Procurement Rules”, as amended.

Taking into account the fact that the service subject to this procurement procedure also provides for the transport from the CA to the treatment facilities of the economic operator, as well as the final product from the operator's premises to the landfill, this criterion requires economic operators to prove that they have at their disposal or that they can be provided with the necessary means to fulfill the contract in order to execute the procurement object.

Since the technical specifications and terms of reference stipulate that the means of transport used for the delivery of new empty containers must not be the same as the one used for the collection of containers filled with waste, waste containers and new empty containers cannot be transported by the same means of transport. The required number of vehicles is minimal, in order to ensure that the transport of containers is carried out in a way that ensures their integrity and cleanliness, in accordance with hygiene and safety rules.

**2.3.3** Economic operators must employ 13 (thirteen) employees employed for the implementation of the contract/s that will be concluded in accordance with the framework agreement, as follows:

- 1 (one) employee Service Manager
- 2 (two) employee drivers
- 4 (four) employee service (loading/unloading)
- 6 (six) employees for the operation of plants and machinery

For the employees required above, the following documents must be submitted:

**For the Service Manager:**

The service manager must be an Environmental Engineer/Environmental Expert and for this employee, the following must be submitted:

- Diploma with the profession of Environmental Engineer/and/or Certificate “On Environmental Impact Assessment and Environmental Audit”;
- Employment contract (valid) as Service Manager;
- E-sig form of the payroll for the last month

**For driver employees**

- Relevant employment contract, (valid)
- Driving license

**For service employees (loading/unloading), and employees for the operation of plants and machinery, please submit:**

- Relevant employment contract, (valid)

*This Criterion is considered fulfilled by completing the form according to Annex 10 of the DT. The supporting documents required above will be submitted by the first qualified bidder, before the publication of the winner notice and the start of the appeal deadlines, or if clarifications are requested by the Contracting Authority.*

**Reasoning:** Based on point 4, of Article 77, of Law No. 162, dated 23.12.2020 “On Public Procurement” and points 4/b and 4/c of Article 41 of the Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended, this criterion requires

economic operators to prove that they have the necessary workforce for the execution of the procurement object, i.e. that they have at their disposal for the fulfillment of this contract.

The criterion for employees is determined by an analysis of the technical specifications, terms of reference, and the processes for the realization of the service subject to procurement.

The service manager is required to organize, manage, divide and supervise the service processes, as well as be responsible for the implementation of all tasks and phases of the service, in accordance with the technical specifications, terms of reference, applicable legal rules and standards in force. The profile required for the service manager is related to the fact that an environmental engineer/environmental expert has the necessary expertise to analyze the various impacts that the treatment of hazardous waste can bring to the environment, including air, water and soil pollution. The environmental engineer plays a key role in the implementation of environmental standards, monitoring emissions and pollution control, as well as in planning for environmental emergencies that may occur.

Based on the analysis of the technical specifications and terms of reference, and considering that among the work processes is the collection of waste containers at the temporary storage points of the health authorities, loading and unloading bins/containers to and from the collection machine, auxiliary workers and workers for the operation of the plants and machinery to be used have been required.

The number of employees has been estimated in accordance with the work processes and tasks to be performed, in accordance with the technical specifications and terms of reference.

The documentation required for employees serves as proof/evidence of meeting this criterion.

2.3.4. The operator must own or rent/use, or through any means of possession recognized by law, the following plant/machineries to enable the treatment of all categories of waste subject to procurement, according to Law No. 10463 dated 22.09.2011 “On integrated waste management”, as amended, as well as the Council of Ministers for the approval of the regulation “On hospital waste management”, (Regulation) as well as machinery for washing and disinfecting containers, as follows:

1. Plant for sterilization treatment (autoclaving technology or equivalent) - 1 piece
2. Plant for incineration disposal - 1 piece
3. Machinery for washing containers 1 piece

To prove the fulfillment of this criterion, the economic operator must have the following supporting documents:

1. Documentation to prove the ownership, loan or rental of the equipment (where the term of rental/use is at least the term of execution of this procurement object);
2. The approvals issued by the Ministry of Tourism and Environment presented in fulfillment of criteria 2.1.1 and 2.1.2 above must be reflected in the act;
3. Catalog or technical sheet or any other technical document of each plant and machinery;
4. CE Declaration of Conformity of each plant and machinery.

**Note:** *The criterion is considered fulfilled by the submission of specific data for each device (including backup ones), through the self-declaration form according to Annex 10 of the DST, including the following data: name of the plant / designation as primary or backup / model / waste streams that it treats and/or disposes of / relevant Permits and Licenses where they are included (from those submitted in fulfillment of criteria 2.1.1 and 2.1.2 above).*

*The supporting documents required above will be submitted by the first qualified bidder, before the publication of the winner's announcement and the start of the appeal deadlines, or if clarifications are requested by the Contracting Authority.*

**Reasoning:** Based on point 4, article 77, of law no. 162, dated 23.12.2020 “On public procurement” and article 41, point 4/ç, of the Council of Ministers no. 285, dated 19.05.2021 “On the approval of the Public Procurement Rules”, as amended, this criterion requires economic operators to prove that they have at their disposal or that they can be provided with the technical equipment to fulfill the contract, necessary for the execution of the procurement object.

Based on Law No. 10463, dated 22.09.2011, “On integrated waste management”, as amended, Law No. 10431, dated 09.06.2011, “On environmental protection”, as amended, Council of Ministers No. 798, dated 29.09.2010, “On the approval of the regulation, ‘On the administration of hospital waste’, Council of Ministers No. 402, dated 30.06.2021, “On the approval of the waste catalog”, plants for the treatment of certain categories of hospital waste are the basic equipment for the successful implementation of this service.

The reflection in the act of approvals issued by the Ministry of Tourism and Environment presented in fulfillment of criteria 2.1.1 and 2.1.2 confirm that these devices are licensed to carry out the waste treatment process from competent authority. This certification is a legal obligation for all equipment that performs these types of processes in the territory of the Republic of Albania and not for the owner or third party, so the request is necessary for the exercise of the activity in question. The focus of this request is on the plant and not on third parties who rent or lend it.

The catalog or technical sheet or any other technical document of each plant and machinery, as well as the CE Declaration of Conformity of each plant and machinery prove their compliance with the required technical specifications.

**2.3.5** The economic operator must have and submit: a contract concluded with an entity permitted by the NEA for the deposit of the final product resulting from the disposal/treatment, which must be active and valid at the time of opening the bids. The entity in question must be authorized in the relevant Environmental Permit to accept the final product resulting from the treatment process with non-incineration technology with code 19 01 and the final product resulting from the treatment process with sterilization technology with code 19 03.

**Reasoning:** Based on point 4, article 77, of law no. no. 162, dated 23.12.2020 “On public procurement” as amended and article 41, point 4/ç, of Council Decision no. 285, dated 19.05.2021 “On the approval of the Public Procurement Rules” as amended, in Council Decision No. 402, dated 30.06.2021, “On the approval of the waste catalog”, and given that based on Council Decision no. 798, dated 29.09.2010, “On the approval of the regulation, ‘On the management of hospital waste’”, hospital structures as waste generators are responsible until the last link of the disposal of the hospital waste they create, the CA requires that the economic operator must submit a contract concluded with an authorized entity according to the law for the deposit of the respective final product resulting from the treatment/disposal processes, which must be active and valid at the time of opening the bids and in the continuation of this agreement until the conclusion of the contract for the implementation of the contract.

These documents are required in order to successfully implement the final disposal of waste as a very important element of the process where it is documented that the EO is in this field of activity and performs this type of service.

**2.3.6** The operator must submit for each type of container according to the standards and requirements of the Technical Specifications and Terms of Reference:

- Catalog or technical sheet,
- Self-declaration for certification and approval of the type of packaging for each type of container (reusable or disposable) referred to VKM no. 798, dated 29.09.2010, “On the approval of the regulation, ‘On the management of hospital waste’”.

**Reasoning:** Based on point 4, article 77, of law no. no. 162, dated 23.12.2020 "On public procurement" and point 4/č article 41, of the Council of Ministers no. 285, dated 19.05.2021 "On the approval of the Public Procurement Rules", as amended, this criterion requires economic operators to prove that they have at their disposal the means and equipment to fulfill the contract, necessary for the execution of the procurement object. Based on Law no. 10463, dated 22.09.2011, "On integrated waste management", as amended, Law no. 10431, dated 09.06.2011, "On environmental protection", as amended, Council of Ministers no. 798, dated 29.09.2010, "On the approval of the regulation, 'On the management of hospital waste'", VKM No. 402, dated 30.06.2021, "On the approval of the waste catalog", hospital waste containers are essential elements in the processes of managing the disposal of hospital waste, such as for their collection, isolation, stacking, and transportation.

**2.3.8** The economic operator bidding must prove and present a certificate (valid and in accordance with the procurement object), as follows:

- SSH EN ISO 14001:2015 "Environmental management systems" or equivalent/equivalent;
- SSH EN ISO 9001:2015 "Quality management systems" or equivalent/equivalent;
- SSH EN ISO 45001:2018 "Occupational health and safety management systems" or equivalent/equivalent.

The relevant certificates must be issued by conformity assessment bodies accredited by the General Directorate of Accreditation or international accreditation bodies recognized by the Republic of Albania, and valid at the time of the tender.

**Reasoning:** The above requirement is based on Article 77, point 1/a), Article 79 of the LPP, Article 44 of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of public procurement rules", as amended.

- ISO 9001:2015 Standard "Quality Management System" - This standard is necessary as it ensures that the economic operator has a structured management system for the continuous quality of the service subject to procurement. Compliance with this standard guarantees that the service implementation processes will be carried out in a controlled, documented manner, minimizing errors/negligence during the treatment and disposal of waste.

- Standard 14001: 2015 on "Environmental Management Systems" – has been set as a criterion taking into account the fact that this Standard is a systematic and quality management process-oriented system to control the significant impacts of business activities on the environment, as well as assessing that the subject of the procurement includes the collection, treatment, transportation, disposal of hospital waste. The provision of the economic operator with this standard is an indicator that the bidder is able to identify, control and minimize its impact on the environment during the implementation of the services subject to procurement.

- Standard ISO 45001 on "Occupational Health and Safety Management Systems" has been set as a criterion in order for the CA to ensure that the bidder performs the service in accordance with the required standards regarding occupational health and safety. It is an indication that the operator protects employees from biological, chemical and physical risks associated with the treatment of hazardous waste, as well as provides training, protective equipment, safety protocols and preventive measures for accidents that may occur during the provision of services.

## **II. Reasoning of technical specifications**

The technical specifications, terms of reference for the implementation of the service subject to procurement, the calculation of the limit fund have been forwarded to the OBP, drafted by the working group appointed by the head of the contracting authority "University Obstetric Gynecological Hospital "Queen Geraldine" Tirana", for whose needs, the Centralized Purchasing



Operator, in the capacity of the Central Purchasing Body, carries out the procurement procedure, in accordance with Law No. 162/2020 "On public procurement", as amended, Council of Ministers No. 531 dated 7.9.2023 "On the establishment of the state joint-stock company "Centralized Purchasing Operator" Sh.a for carrying out special public procurement procedures, on behalf and for the account of the Prime Minister's Office, Ministries and Dependent Institutions", as amended.