

**MINISTRY OF HEALTH SOCIALIST REPUBLIC OF VIETNAM**  
**Independence - Freedom - Happiness**

No. 14/2020 / TT-BYT

Hanoi, July 10, 2020

**CIRCULARS**

**Stipulating a number of contents in bidding for medical equipment  
in public health facilities**

*Pursuant to the Law on Bidding No. 43/2013 / QH13 dated November 26, 2013;*

*Pursuant to the Government's Decree No. 63/2014 / ND-CP dated June 26, 2014*

*Government details the implementation of a number of articles of the Bidding Law regarding home selection bid;*

*Pursuant to the Government's Decree No. 36/2016 / ND-CP dated May 15, 2016*

*Medical equipment management government is amended and supplemented by Decree No. 169/2018 / ND-CP dated December 31, 2018 and Decree No. 03/2020 / ND-CP dated January 1, 2020;*

*Pursuant to the Government's Decree No. 75/2017 / ND-CP dated June 20, 2017*

*Government regulations on the functions, tasks, powers and organizational structure of the Ministry of Health;*

*At the request of the Director of Department of Medical Equipment and Medical Works,*

*The Minister of Health promulgates the Circular providing for a number of events in the fight medical equipment contracting at public medical establishments.*

**Chapter I**

**GENERAL RULES**

**Article 1. Scope**

This Circular provides a number of contents on:

1. Category and tendering to groups of medical equipment bidding packages.
- Report on bidding for medical equipment.
3. Prepare bidding documents, request for proposals.
4. Medical equipment procurement contractor selection plan.

## **Article 2. Scope of application**

1. This Circular applies to the purchase of medical equipment at establishments  
Public health departments use one of the following funding sources:

- a) State budget recurrent expenditure sources in accordance with the Law State budget assigned by competent agencies in budget expenditure estimates annual books of agencies and units (including additional sources in the year);
- b) Funding for the implementation of the national target program in the case of execution in the form of an investment project that does not form;
- c) Credit capital guaranteed by the State, other capital managed by the State;
- d) Official development assistance (ODA) capital: Loans, no aid Balanced reimbursement in regular expenditures of the state budget; aid source, sponsorship by foreign non-governmental organizations, individuals and organizations at home and foreign countries belonging to the state budget (except for the case of international treaties on ODA and concessional loans that the Socialist Republic of Vietnam is a member has other rule);
- dd) Revenue from fees and charges is used in accordance with the law on fees, fees;
- e) Funding sources from collection of non-business activities and development fund for public activities industry, reward fund, welfare fund, other legal fund as prescribed by law in public non-business units;
- g) Health Insurance Fund Sources;
- h) Other legal sources of income as prescribed (if any).

2. This Circular does not apply to cases of equipment procurement medical equipment ordered or assigned by the State under the provisions of the Decree Decree No. 32/2019 / ND-CP dated April 10, 2019 of the Government on assignment task, order or bid to provide public products or services using the bank State books from recurrent funding sources.

3. Private medical examination and treatment establishments participating in medical examination and treatment Health insurance can refer to the application of this Circular in the match medical equipment contractor.

## **Article 3. Application of the provisions of the law on bidding**

Provision and posting of bidding information; term, process supply issuing and posting bidding information; costs in the contractor selection process;

archiving documents during the contractor selection process; approval of home selection plan bid; bidding process; contractor selection form; method of home selection  
Contracts and contracts shall comply with the provisions of the Law on Bidding No. 43/2013 / QH13, Decree No. 63/2014 / ND-CP dated June 26, 2014 of the Government on regulations

detailing the implementation of a number of articles of the Bidding Law regarding contractor selection (hereinafter called abbreviated as Decree No. 63/2014/ND-CP) and other content not specified in

This Circular complies with the relevant law on bidding.

**Article 4. Provisions on subgrouping and tendering to groups of packages  
medical equipment contractor**

1. Provisions on subgroups

Medical equipment bidding packages may contain one or more types of equipment  
Medical devices and each category of medical equipment can be classified into groups  
as follows:

a) Group 1 includes medical equipment that simultaneously satisfies the following criteria:

- Enclosed with at least 02 of the countries in Appendix I

This Circular (hereinafter referred to as the reference country) grants the free sale certificate;

- Made in the reference country or made in Vietnam.

b) Group 2 includes medical equipment that simultaneously satisfies the following criteria:

- Be granted a free sale certificate by at least two reference countries;

- Not produced in the reference countries or made in Vietnam.

c) Group 3 includes medical equipment that simultaneously satisfies the following criteria:

- Be granted a free sale certificate by at least 01 reference country;

- Made in the reference country or made in Vietnam.

d) Group 4 includes medical equipment that simultaneously satisfies the following criteria:

- Be granted a free sale certificate by at least 01 reference country;

- Not produced in the reference countries or made in Vietnam.

dd) Group 5 includes medical equipment that simultaneously satisfies the following criteria:

- Having a circulation number in Vietnam (including cases in which it is issued  
certificate of circulation registration);

- Made in Vietnam.

e) Group 6 includes medical equipment not falling into the specified cases

at points a, b, c, d and dd of this Clause.

2. Determination of the country of manufacture of medical equipment is based on the recorded information  
on one of the following papers:

a) Import permit;

b) The registration number (including the sale registration certificate);

c) Certificate of free sale and certificate of eligibility

quality management ISO 13485.

3. Provisions on tendering to groups of medical equipment bidding packages

Contractors with medical equipment that meet the criteria of which group are eligible to participate

If the contractor falls into that group, the medical equipment that meets the criteria for many groups is the contractor  
Bidding into one or more groups and must have bid prices uniformly in

all groups to which the bidder bids (no category criteria apply medical equipment means a system consisting of many single medical equipment), specifically as follows:

- a) Medical equipment meeting the criteria in group 1 shall be bid in group 1 and Groups 2, 3, 4, 5, 6;
- b) Medical equipment that meets the criteria in group 2 to be bid in group 2 and groups 3, 4, 5, 6;
- c) Medical equipment that meets the criteria in group 3 to be bid in group 3 and groups 4, 5, 6;
- d) Medical equipment that meets the criteria in group 4 to be bid on group 4 and groups 5, 6;
- dd) Medical equipment that meets the criteria in group 5 to be bid in group 5 and group 6;
- e) Medical equipment that does not meet the criteria in groups 1, 2, 3, 4 and 5 is only be bid to group 6.

**Article 5. Report on medical equipment bidding**

1. After the contractor selection result is approved, within 20 On a date, the head of the medical facility is responsible for reporting on the result of contractor selection the form in Appendix II enclosed herewith, for medical equipment special use and according to the form in Appendix III issued together with this Circular for with other medical equipment, to the competent authority to approve the selected plan Contractor and Ministry of Health (Planning and Finance Department).

2. Within 10 working days from the date of receiving report on results Selection of contractors from medical establishments, agencies competent to approve plans

contractor selection and the Ministry of Health (Department of Planning and Finance) is responsible for posting publicity on the Portal.

3. When the contractor has violated the bidding process for equipment supply medical facilities and medical establishments shall report to competent authorities for handling according to regulations law on bidding and handling of violations of law. Result of handling violations must sent to the Ministry of Health (the Department of Planning and Finance) within 05 working days, since the violation results are made according to the form specified in Appendix V issued together According to this Circular to synthesize and publish, as a basis for the units to consider and evaluate price, contractor selection in the next visit.

**chapter II**

**CONTRACTOR SELECTION PLAN**

**Article 6. Make a plan to select the medical equipment contractor**

In addition to complying with the provisions of the Law on Bidding No. 43/2013 / QH13, Decree Decree No. 63/2014 / ND-CP and related bidding documents, the formulation Contractor selection plan must comply with the following provisions:

1. Contractor selection plan is formulated annually or when there is a team need Contractor selection organization with the following grounds:

a) Regarding the bidding package for the purchase of special-use medical equipment: Estimation Procurement is based on the assigned funding sources and the norm of medical equipment Specialized use is approved according to the provisions of Circular No. 08/2019 / TT-BYT May 31, 2019 The Minister of Health guides standards and regulations level of use of specialized machinery and equipment in the health sector (hereinafter referred to as short) is Circular No. 08/2019 / TT-BYT);

b) For the procurement of other medical equipment: The estimate of procurement is made based on funding sources, the actual purchase and use of medical equipment in the previous year projected demand for using medical equipment in the year for planning.

2. The name of the bidding package must reflect the nature, content and scope of the work of the package; consistent with the content stated in the project, estimate of procurement. School In the contractor selection plan, the name should be stated in a contract with many separate parts show the basic content of each part.

#### **Article 7. Guiding the formulation of bidding documents, equipment request documents medical**

In addition to complying with the provisions of the Law on Bidding No. 43/2013 / QH13, Decree Decree No. 63/2014 / ND-CP and related bidding documents, upon construction construction of bidding documents, request for proposals of entities must:

1. Carrying out the grouping of medical equipment according to the provisions of Article 4. This circular, in which one category of medical equipment can be classified one or more different groups to suit professional requirements, use needs use and funding.

2. Based on professional requirements, demand to build requirements engineering of medical equipment. Particularly for specialized medical equipment According to Circular No. 08/2019 / TT-BYT, the construction of equipment technical requirements medical equipment as prescribed in Appendix IV issued with this Circular.

3. Request the bidder to provide the number of receipts for the eligibility to purchase the sale of medical equipment, the registration number or the import permit number appropriate to the site Bidding medical equipment according to the provisions of Decree No. 36/2016 / ND-CP dated 15 May 2016 of the Government on medical equipment management was amended and supplemented Supplemented by Decree No. 169/2018 / ND-CP dated December 31, 2018 and Decree No. 03/2020 / ND-CP dated January 1, 2020 of the Government.

4. Specifying the contractor's responsibility in handing over, installing, digging create and guide use to ensure efficiency, quality and safety for patients and staff use.

5. No requirements or direction may be given to the bidder's participation

the bid must offer imported goods when the goods are domestically produced or  
 The assembly meets the quality, quantity, price requirements and must comply with the regulations  
 concessional content (criteria, calculation of the incentive value and documents evidencing  
 smart) in accordance with the law on bidding.

6. Medical equipment bid regulations must be provided by one  
 in the following organizations and individuals:

- a) The organization or individual is the holder of the free sale number of the medical equipment;
- b) Organizations and individuals authorized by the holder of the registration number of the free sale of medical equipment permission;

c) Organizations and individuals defined by organizations and individuals specified at Point b of this Clause authority;

d) Organizations and individuals authorized by the owner of the medical equipment;

dd) Organizations and individuals defined by organizations and individuals specified at Point d of this Clause authority;

e) Organizations and individuals defined by organizations and individuals specified at Point dd of this Clause authority;

g) Organizations and individuals whose names are on the medical equipment import Permit;

h) Organizations and individuals defined by organizations and individuals specified at Point g of this Clause authority;

The authorization must comply with civil law.

#### **Article 8. Package price**

1. The bidding package price is built on the basis of the total investment or the forex estimate for a project, the bidding package price is the total value of the bidding package which is correctly and fully calculated costs for implementing the package, including contingency costs, fees, charges and taxes.

2. If a bidding package is divided into many parts, in addition to recording the total value of bidding package, each part must clearly state the list, quantity, unit, unit price and total value of such part as prescribed in Clause 1 of this Article.

3. When making cost estimates for bidding packages, medical establishments must consult equipment prices Successful candidates within the previous 12 months have been posted on the Portal electronic agency competent to approve contractor selection plan and ministry Medical as a basis for setting the unit price of each medical equipment, specifically as follows:

a) The planned price of the medical equipment must not be higher than the winning price of the medical equipment performed or the announced winning bid price. Case The higher price must have specific explanations and explanations;

b) For medical equipment without winning bid prices posted,  
 When preparing and determining the bidding package price in the contractor selection plan, it should be based on guiding documents of the Law on Bidding No. 43/2013 / QH13, Decree No. 63/2014 / ND-CP and related bidding documents on price setting

the bidding package is consistent with the price of such medical equipment on the market at the time contractor selection planning.

### **Article 9. Documents for approval of contractor selection plan**

In addition to complying with the provisions of the Law on Bidding No. 43/2013 / QH13, Decree Decree No. 63/2014 / ND-CP and related bidding documents, documents

The request for approval of the minimum contractor selection plan includes:

1. The contractor selection plan document for approval.
2. Relevant legal documents and records.
3. Summary report on the implementation results of the contractor selection plan, the situation use of the medical equipment of the preceding year (if any) and the summary explanation of the succession Contractor selection plan is currently submitted.
4. The documents as a basis for planning contractor selection site medical equipment specified in Clause 1, Article 6 of this Circular.
5. Minutes of the meeting of the Scientific Council of the medical facility to unify the Cabinet content on the plan, usage needs, list, quantity, technical requirements and projections medical equipment math proposed investment with the full participation of all the following components: great representatives of the relevant faculties and functional departments, the representatives of the specialized units used Medical equipment.
6. Documents used as a basis for setting the price of the equipment package medical equipment specified in Article 8 of this Circular.

## **Chapter III TERMS ENFORCEMENT**

### **Entry into force**

This Circular takes effect on September 1, 2020.

### **Article 11. Transition Terms**

1. For contractor selection plans approved before date  
This Circular takes effect, it is allowed to continue the implementation according to the plan approved by competent authorities and must report on the results of implementation according to regulations specified in Article 5 of this Circular.
2. As for contractor selection plans, which have been submitted to competent authorities in advance  
The effective date of this Circular but has not yet been approved may continue procedures for organizing the plan appraisal and approval if the plan contents do not have regulations regulations contrary to the provisions of this Circular and must report on the results of the implementation according to the regulations specified in Article 5 of this Circular.

**Article 12. Organization of implementation**

Heads of medical facilities are responsible for:

1. Direct the Medical Supplies and Equipment Division or the medical equipment management division  
At the medical facility, synthesize the needs, develop the procurement list, plan and estimate  
medical equipment and advise heads of medical facilities on configuration and features  
specifications, usability, standards and technology generation and terms  
ensure safety, train staff to use, install technical infrastructure to put the equipment  
being put into operation, meeting professional requirements and promoting investment efficiency.

2. Based on the annual quantity of medical equipment procurement and the need for use  
use of medical equipment of faculties, professional rooms and units, subject matter  
Export and advise the Medical Supplies and Equipment Department, the medical equipment management division  
and Scientific Council opinions at health facilities for decision and construction responsibility  
plan to use medical equipment of the unit.

In the course of implementation, if any problems arise, agencies and organizations are requested.  
Individuals report to the Ministry of Health for consideration and resolution./.

**Recipients :**

- Government Office (KGVX Department, Official Gazette, Government portal);
- Ministry of Justice (Department of Examination of Legal Normative Documents);
- Ministries, Ministerial-level agencies, Governmental agencies;
- People's Committees of provinces and cities directly under the Central Government;
- Department of Health of provinces and cities directly under the Central Government;
- Units under the Ministry of Health;
- Vietnam Social Insurance;
- Health sector;
- Vietnam Medical Equipment Association;
- Departments, Departments, General Departments, Ttra Ministries, Office Ministries - MOH;
- Information portal of the Ministry of Health;
- Save: VT, PC, TB-CT.

**KT. MINISTER  
DEPUTY**

**Truong Quoc Cuong**

Issuing agency: Ministry of Health

**Appendix No. I****LIST OF REFERRED COUNTRIES**

*(Issued together with the Circular No ... / 2020 / TT-BYT dated... month... year of 2020 of*



*Health Minister)*

1. European countries:

- Republic of Austria;
- Republic of Poland;
- Republic of Portugal;
- Republic of Bulgaria;
- Republic of Croatia;
- Republic of Estonia;
- Republic of Hungary;
- Greek Republic;
- Republic of Ireland;
- Republic of Latvia;
- Germany;
- Lithuanian Republic;
- Republic of Malta;
- Republic of Finland;
- French Republic;
- Republic of Romania;
- Czech Republic;
- Republic of Cyprus;
- Slovak Republic;
- Republic of Slovenia;
- Republic of Spain;
- Italian Republic;
- Grand Duchy of Luxembourg;
- Swiss Federation;
- UK;
- The kingdom of Belgium;
- Kingdom of Denmark;
- Kingdom of the Netherlands;
- Kingdom of Sweden.

2. United States of America.

3. Japan.

4. Australian Commonwealth Competition.

5. Canada.

**Appendix No. II**

**FORM OF REPORT ON CONTRACTOR SELECTION OF SPECIAL USE MEDICAL EQUIPMENT SUPPLYING CC**

*(Issued together with the Circular No ..../ 2020 / TT-BYT dated... .. month.... .. year 2020 of the Minister of Health)*

**NAME OF THE REPORTING UNIT**

**SOCIALIST REPUBLIC OF VIETNAM**

**Independence - Freedom - Happiness**

No. : .....

*(Place name), date .... month .... year 20 ...*

**REPORT ON CONTRACTOR SELECTION OF SPECIAL USE MEDICAL EQUIPMENT**

Time from date... .. to date .....

Dear: .....

Contractor selection plan				Information general				Result											
No	Name	Page set	be	Source	Number	Name	Race	Number	save	Year	Country	The firm	The firm/	Application	Number	Unit	price	Configuration,	Unit
				invest	amount	concentration	(model)	or	license	real	real	real	country	taste	amount	hit	bid	feature	hit
				level	level	level	level	number	number	export	export	export	master	count	count	count	(VND)	basic	basic

medical

medical

import password

Organic

Decision approving the contractor selection plan:
No... / QD-... date... month... year...
Package's name: ..... Contractor selection method: .....

Decision to approve contractor selection result:
No... / QD-... date... month... year...
Package's name: .....

first
2
...

THE REPORTING PERSON

(sign, write title, working unit)

UNIT HEADS

(sign and stamp)

Recipients:

- As above;
- Save: VT

twelfth

Appendix No. III
FORM OF REPORT ON CONTRACTOR SELECTION OF OTHER MEDICAL EQUIPMENT SUPPLIERS
(Enclosed with the Circular No: .... / 2020 / TT-BYT dated... .. month... .. year 2020 of the Minister of Health)

NAME OF THE REPORTING UNIT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No. : .....

(Place name), date .... month .... year 20 ...

REPORT ON CONTRACTOR SELECTION OF OTHER MEDICAL EQUIPMENT SUPPLIERS

Time from date... .. to date .....

Dear: .....

Table with columns: Contractor selection plan, Information general, Result. Includes sub-columns for Name, Fees, Number, Application, Unit price, Fort, Source, Number, Name, Race, Number saved, Year, Country, The firm, The firm, Application, Unit price, Feature, Unit.

Decision approving the contractor selection plan:
No... / QD-... date... month... year...
Package's name: ..... Contractor selection method: .....

Decision to approve contractor selection result:
No... / QD-... date... month... year...
Package's name: .....

THE REPORTING PERSON

(sign, write title, working unit)

UNIT HEADS

(sign and stamp)

Recipients:

- As above;
- Save: VT, ...

Appendix IV
CONTENTS TECHNICAL REQUIREMENTS

**OF SPECIAL USED MEDICAL EQUIPMENT**  
(Issued together with Circular No. / 2020 / TT-BYT dated month year 2020  
of the Minister of Health)

Technical requirements for specialized medical equipment include the following 4 parts:

- 1. General requirements:** Required production year, 100% new, equipment standard, quality management system standards of manufacturers (ISO 13485, ISO 9001 ...), required the equipment's operating environment (temperature, humidity), power source used.
- 2. Requirements for configuration:** Specify system / machine ... (name of medical equipment) attached standard and specifying the complete list of the main components of the medical device, number quantity, unit of calculation.
- 3. Technical specifications:** Stating the following minimum requirements:
  - a) Stating requirements on the purpose of use, principles of operation and technology of Medical equipment;
  - b) Stating requirements on technical specifications (stating technical specifications in the given order listed in the section on the configuration requirements of the medical device);
  - c) The specifications represent the function of the equipment, and also the requirements detailed bridge of equipment (if any):
    - Requirements on structure: sensors, materials for fabrication, design ...
    - Requirements for control: Control principle (digital, mechanical ...), isometric methods (by computer, buttons on the machine, console ...), functions control (by software ...)
    - Display requirements: Display by mechanical indicator, by LED light, screen: state screen type, size, brightness (if any), resolution (if any) ...
    - Requirements for safety functions, safety warning.
    - Requirements for verification and calibration.
    - Requirements for application software, control software.
    - Requirements for connectivity between the equipment's components, connecting with the device is different.
    - Requirements on the ability to upgrade and update software and technology of the device.
- 4. Other requirements:** Stating requirements for warranty, maintenance, time of supply, installation install, test, manual, train, supply spare parts and consumables depreciation, commercial terms.

**Appendix V**

**FORM OF AUCTION VIOLATION REPORT**

(Enclosed with the Circular No: .... / 2020 / TT-BYT dated... .. month.... .. year 2020 of the Minister of Health)

**NAME OF THE REPORTING UNIT**

No. : .....

**SOCIALIST REPUBLIC OF VIETNAM**

**Independence - Freedom - Happiness**

(Place name), date .... month .... year 20 ...

**REPORTING VIOLATION OF CONTRACTOR  
IN THE AUCTION, SUPPLY OF MEDICAL EQUIPMENT FOR THE YEAR ...**

To: .....

Comply with the provisions of the Circular No. .... / 2020 / TT-BYT dated month year 2020, (*Name of the Unit*) reporting the violation of the cont  
In bidding, supplying medical equipment for the year .... as follows:

<b>Contractor's name</b>	<b>Name of equipment Medical bidders violate</b>	<b>Circulation number / Entry license number import of medical equipment violate</b>	<b>Unit name tenderer</b>	<b>Content violations</b>	<b>Note</b>
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*Note: It is required to specify violations of the contractor during the participation in the bid, violations in the performance of the contract to provide the si  
The contractor's medical equipment shall base itself on the current regulations on bidding for medical equipment and other relevant regulations.*

**THE REPORTING PERSON**

*(sign, write title, working unit)*

**UNIT HEADS**

*(sign and stamp)*

**Recipients:**

- As above;
- Save: VT.