

28 March 1995

Standard Guide for the Overall Greatest Value Evaluation Methodology  
Concerning Procurement of Medical Technology Products and Services  
(Understandings among related ministries and agencies concerned in procurement)

This standard guide has been compiled as a guide to the basic operational points concerning operation within the rules of the heads of each of the government ministries and agencies after consultation with the Minister of Finance, to ensure that procurement entities contribute to improving efficiency of administrative processing in cases where the overall-greatest-value evaluation method is used for procurement.

Section 1

Rules of the Heads of all Government Ministries and Agencies (After Consultation with the Minister of Finance)

I. Scope of Application

The rules will be applied, in the case where the following designated computer products and services are procured and the issuance of the notice of invitation to tender is made after 1 July 1995.

Subject of Procurement
<p>1 Medical Technology Products</p> <p>(1) All equipment and instruments, medical goods and dental materials included in Annex (1) to the Drugs, Cosmetics and Medical Instruments Act excluding products which are used for animals.</p> <p>(2) Medical products used for external medical examinations as stipulated in Par. 2 of Article 56 of the Enforcement Regulations of the Drugs, Cosmetics and Medical Instruments Act.</p>
<p>2 Medical Technology Services</p> <p>Plans for "Medical Technology Products" and "Software mainly for medical technology products".</p>
<p>(Note): The above-mentioned are referred to as medical technology products and</p>

services (hereafter referred to as products etc.) as applied in the "Measures on Japanese Public Sector Procurement of Medical Technology Products and Services" (A decision on 28 March 1994 of the 21st Meeting of the Committee for Drawing Up and Promoting the Action Program. Hereafter referred to as "the Measures". (The Measures on Japanese Public Sector Procurement of Medical Technology Products and Services Operational Guidelines with respect to the "Measures on Japanese Public Sector Procurement of Medical Technology Products and Services" were decided on 7 October 1994 in the 22nd Meeting of the Committee for Drawing Up and Promoting the Action Program.))

#### Scope of Application

- 1 In remodeled products or services the projected procurement price will not be less than 100,000 SDRs. (Although the point at which the announcement for the request for the submission of comments for products and services exists in international markets, in order to satisfy the fair requests of the procurement entities, there are some items for which it is necessary to remodel the process considerably for function or main physical characteristics.)
- 2 In specially developed products or services, the projected procurement price is not less than 100,000 SDRs. (A form which will satisfy efficiency demands does not exist in the international markets, and in particular to fulfill the fair procurement requests of procurement entities, products and services must be developed)
- 3 With the exception of cases where products of a unit price of below 500 SDRs, or the projected procurement price shall be in excess of 385,000 SDRs a large volume of products or services has been made. (When a request for the submission of comments, or a Notice of Procurement exists in the international market) (However, the threshold will be lower in FY 1995 to 800,000 SDRs, in FY 1996 to 600,000 SDRs and in FY 1997 to 400,000 SDRs)
- 4 In addition to the above 1-3, when procurement entities decided to make a bid application where the overall-greatest-value evaluation is suitable, a report is made to the Minister of Finance no less than thirty days prior to the date of the Notice of Procurement.

(Note) 1. In cases where this bidding method is applied, the exchange of SDRs into

Japanese currency is calculated based on the following method which is based on the exchange amount publicly notified by the Minister of Finance, which in turn is based on Article 2 of the regulation on "Cabinet Order Stipulating Special Procedures for Government Procurement of Products or Specified Services" (Government Ordinance No. 300 of 18 November 1980)

Conversion of SDRs into Japanese currency =

130,000 SDRs in Japanese currency multiplied by OO/13

(Note) OO indicates the SDRs in units of 10,000, which are the object of conversion.

2. With regard to adjustment of the amount converted to Japanese currency, 500 SDRs are rounded up to 1000 yen, 100,000-600,000 SDRs are rounded up to 1,000,000 yen and 800,000 SDRs are rounded up to 10,000,000 yen.

## II. Bidding Method

- 1 Upon application bidders must supply information on price, performance, function and technology and of the tenders that conform to the following requirements, and through the overall-greatest-value method detailed in III, the tender which receives the highest value will be the successful bidder.
  - (1) The bid price is within the scope of the limits of the projected price.
  - (2) The performance, function and technology concerning the bid (hereafter referred to as performance etc.) fulfill the required minimum stipulations of articles that are viewed indispensable in the performance etc., required stipulations (referred to below as technical specifications), which are enumerated in the Notice of Procurement (including relevant tender documentation, detailed below).
- 2 If the bidder with the highest value as explained in 1. above exceeds two persons, the successful bid will be decided by the drawing of lots.

## III. The Overall Greatest Value Evaluation Method

- 1 The evaluation method of performance etc., is as detailed hereunder.
  - (1) The technical specifications, which are the object of evaluation, have been designed as evaluation articles from the viewpoint of administrative and business needs to respond to the pertinent procurement aims and contents. They are divided into those articles viewed as essential and other articles.
  - (2) With regard to essential articles, the minimum requirements should be shown article by article and the bids will fail if they are not met. If they are met, basic points will be designated, and additional points will be given to the specifications that surpass the minimum level.

(3) Articles other than those considered essential will be designated additional points by article upon evaluation.

(4) The points in each of the evaluation articles are decided by their necessity and importance.

2 The overall evaluation relating to price and performance etc., results in a value which is attained by dividing the total points for the performance etc., of evaluation categories in the bidders' applications, by the tendered bid price concerned.

#### IV. Others

In cases where this bidding method is applied, it should be made clear in the notice of invitation to tender that the determination of the successful tender will be made through the greatest overall greatest value method and the characteristics of this method.

### Section 2 Guidelines Concerning Overall Greatest Value Evaluation

#### I. General Matters

1 The compilation of criteria for overall greatest value evaluation, while referring to the data and comments gained through such methods as the submission of comments, is based on "the Measures" and is designed to ensure transparency and fairness.

2 Technical requirements and criteria for the award of contracts should be specified in the tender documentation, and that notion should be made in the notice of invitation .

3 In cases where technical requirements and criteria pertaining to bidding evaluation are stipulated in documents relating to specifications (hereafter specification documents) and documents relating to overall evaluation (hereafter overall evaluation standards), these are delivered immediately as part of the tender documentation, in response to requests from suppliers.

#### II. Technical Requirements

1 Technical requirements are divided into those that are essential and other stipulations, and are clearly specified in the tender documentation (including specification documentation).

2 Technical requirements are based on their necessity and importance upon procurement and are established in a suitable fashion while referring to data and comments gained through the procedures pertaining to the submission of comments.

- 3 Essential requirements are limited to those necessary minimum contents needed in practice by the procuring entities.
- 4 Requirements other than those considered essential are limited to those articles for evaluation as laid down in the overall evaluation criteria and those articles not subject to evaluation are not listed.
- 5 In the case when, as the results of the data and comments gained from the procedure of the submission of comments, etc., there are performance-related proposals through different methods from suppliers and any of the proposals could be adopted, the technical requirements are established not to exclude any specific supplier and consideration is duly given so that it is possible each suppliers performance can be evaluated.
- 6 Technical requirements which can be quantified (performance which can be quantified), are in principle specified as figures, and when it is inevitable that they be specified qualitatively , they are recorded to the most specific and detailed extent possible.

### III. Evaluation Criteria

- 1 Concerning criteria pertaining to bidding, evaluation articles, distribution of points (basic points and points given upon evaluation (hereafter referred to as "additional points")) and other articles necessary to evaluation are made clear in the tender documentation (including the overall evaluation criteria).
- 2 Evaluation articles and distribution of points are based upon their necessity and importance upon procurement and are established in a suitable fashion while referring to the performance etc., of products etc. that will be practically possible to introduce and have been supplied through the procedure of the submission of comments, etc.
- 3 In light of importance and necessity for procurement, items for which it is pointless to surpass the scope of necessary evaluation are excluded from evaluation.
- 4 In essential evaluation articles also, in light of the importance and necessity for procurement, it is sufficient that they fulfill minimum requirements and even if the necessary minimum is exceeded, which are beyond the scope of evaluation, no additional points are accrued.
- 5 Evaluation articles should be made as detailed and as specific as possible for the contents of evaluation. In this case, with regard to those items which can be shown in a scope (maximum figure) which is evaluated quantitatively, this should be notified in each

evaluation article.

- 6 The proportional distribution of the sum of basic points and sum of additional points shall be established suitably, ensuring the purpose and usage of products, etc. to be procured.
- 7 Given that the procurement details for medical technology equipment and services are diverse, it is difficult to list all the possible evaluation articles in detail. However, the guideline evaluation articles are illustrated below.

In cases where specific evaluation articles are established, the articles are placed in the contract pertaining to procurement and the contents limited to those that can be secured, with those articles that cannot be secured not being subject to evaluation articles.

(1) Articles relating to Performance, Function etc., and other Technological Aspects, etc.

(i) Performance and Function

Evaluation of processing and analysis capabilities of products, etc.

(ii) Environmental Requirements

Evaluation of the environmental requirements in accordance with the introduction of products, etc., such as power source facility, air conditioning facilities, external measuring methods and weighing facilities, etc., and noise and vibration environmental harmonization conditions.

(iii) Reliability

Evaluation of reliability of products, etc., through operating conditions, results, etc.

(iv) Safety

Evaluation of the safety of patients and operators and medical safety measures.

(v) Maintenance

Evaluation of ease of maintenance, information security, and system monitoring of products, etc.

(vi) Flexibility

Evaluation of expandability and compatibility for products, etc.

(vii) Operability

Evaluation of automation measure and ease of operation of products, etc.

(viii) Others

(2) Articles relating to technological aspects of suppliers

(i) Technological Capability

Evaluation knowledge, capacity and system development of the state-of-the-art technology.

(ii) Maintenance System

Evaluation of maintenance network, time to response from damage call, technical capabilities of maintenance personnel, number of personnel, etc.

(iii) Knowledge

Evaluation of knowledge, etc., relating to the system as a whole for the item which is the target of procurement.

(iv) Results Including Production

Evaluation of production, development or supplied results of the products concerned, etc., and of similar products.

(v) Reliability

Evaluation of reliability of suppliers, including reliability for quality control, official qualifications, security systems, employee education, etc.

(vi) Others

(3) Others

In addition to the above, other appropriate evaluation articles shall be established as the occasion arises.

#### IV. Evaluation

- 1 Bidding evaluation shall be based on the tender documentation (including specifications and overall evaluation criteria) and performance etc., which is not specified in the tender documentation will not be evaluated.
- 2 The evaluation of performance etc., will be undertaken appropriately in a just and fair examination by the procurement entities.

Furthermore, the investigation undertaken will be of a common criteria for all bidders and there will be no specific methods adopted for evaluating specific bidders.
- 3 With regard to essential articles of evaluation, it will be judged whether or not the minimum requirements as specified in the essential stipulations in the tender documentation (including specifications) are fulfilled and then passed or failed. With regard to those tenders that pass, the basic points and additional points will be given, based on the tender documentation (including the overall evaluation standards).
- 4 With regard to articles of evaluation other than those considered essential, it will be judged whether or not the non-essential requirements in the tender documentation (including specifications) are fulfilled. If the requirements are met additional points will be awarded based on the tender documentation (including the overall evaluation criteria).
- 5 Evaluations pertaining to qualitative evaluation articles shall be undertaken with due rationality.
- 6 Concerning evaluation of performance etc., in the case where tests are enforced for tendered products, in order to ensure that the process is undertaken in a fair and

non-discriminatory manner, contents and methods of the tests concerned are clarified in the tender documentation.

## V. Others

### 1 Recording of a Successful Bid etc., and Information Provision

- (1) With regard to a result where performance etc., evaluation relate to the bid application in the overall evaluation or in the case of a successful bid, recording shall be made immediately. In particular, with regard to the results of inspection of technical requirements, each evaluation article and their outcome and the reasons for outcomes shall be recorded, and appropriate responses to complaints, etc., from suppliers shall be made.
- (2) Where requests are made from unsuccessful bidding suppliers for information on the successful bid, information will be provided on the relative merits of the successful bid (points gained for bid price and performance etc., by the said supplier and the successful bidder).

### 2 Ensuring Evaluation Contents

- (1) With regard to performance etc., evaluated in the overall evaluation, all details of these shall be described in contracts to ensure they are carried out.
- (2) For the inspection on the supply time for products etc., it shall be ensured that the evaluated contents are met.