

[lick here for the Trade Guide](#)

apan Medical Technology Arrangement (1994)

EMBASSY OF APAN

WASHINGTON, D.C.

November 1, 1994

Dear Secretary Brown:

With regard to the procurement of medical technology products and services in the apapanese public sector market, I am pleased to state the following upon instructions from my Government.

The Government of apapan reaffirms the Framework for a New Economic Partnership established by the "oint Statement on the apapan-United States Framework for a New Economic Partnership" of the Heads of the Governments of apapan and the United States on uly 10, 1993 (hereinafter referred to as the "Framework"). The goals of the Framework are to deal with structural and sectoral issues in order substantially to increase access and sales of competitive foreign goods and services through market-opening and macroeconomic measures; to increase investment; to promote international competitiveness; and to enhance bilateral economic cooperation between the United States and apapan.

To accomplish these goals with respect to apapanese public sector procurement of medical technology products and services, the Government of apapan has adopted the "Measures Related to apapanese Public Sector Procurement of Medical Technology Products and Services" (hereinafter referred to as the "Measures") and the "Operational Guidelines with Respect to Measures Related to apapanese Public Sector Procurement of Medical Technology Products and Services" (hereinafter referred to as the "Guidelines"), attached as Appendices A and B respectively, with the aim of significantly increasing access and sales of competitive foreign medical technology J products and services in the apapanese public sector procurement market.

Assessment of the implementation of the Measures and Guidelines, as well as the evaluation of progress achieved, will be based on the overall consideration of the following qualitative and quantitative criteria. These qualitative and quantitative criteria will be considered as a set, and no one criterion will be determinative of the assessment of the Measures and Guidelines, or the evaluation of progress achieved. These criteria do not constitute numerical targets, but rather are to be used for the purpose of evaluating progress achieved toward the goals of the Framework and the goals of this sector, as set forth above.

1. QUANTITATIVE CRITERIA

Annual evaluation of progress in the value and share of procurements of foreign medical technology products and services covered by the Measures and Guidelines to achieve, over the medium term, a significant increase in access and sales of competitive foreign medical technology products and services, by:

1.1 Annual value and share of procurements of foreign medical technology products and services covered by the Measures and Guidelines, evaluated by reference to recent trends in the value, rate of growth and share of procurements of foreign medical technology products and services, and the total value of procurements covered by the Measures and Guidelines;

NOTE In the initial years of consultations (before multiple years of data have been collected) it will be necessary to consider recent Kanpo data. J

1.2 Annual review of entities producing foreign direct technology products and services covered by the Measures and Guidelines, in addition to the total number of entities producing foreign direct technology products and services covered by the Measures and Guidelines;

1.3 Annual review and evaluation of contracts awarded as a result of a decision in singling out;

1.4 Annual review of tender submission and foreign supply; and

1.5 Review of competitive bids of foreign direct technology products and services.

2. QUALITATIVE CRITERIA

2.1 Full and non-discriminatory access to procurement information by foreign suppliers at all stages of the procurement process, as provided in the Measures and Guidelines;

2.2 Results of the reviews conducted by the Procurement Review Board;

2.3 Full notification of all requirements of the Measures and Guidelines and terms, in addition to those mentioned above;

2.4 Efforts by foreign suppliers to utilize procurement opportunities, including commitments on draft specifications; and

2.5 Market conditions, including exchange rates.

The Government of Japan will keep the Measures and Guidelines under continuous review. The Government of Japan and the United States will meet in June 1995 and annually thereafter, or at any time upon the request of either Government, to discuss any matters related to the Measures and Guidelines, including assessment of implementation of the Measures and Guidelines and evaluation of progress achieved toward the goals of the Framework and the goals of this sector, as set forth above. Such consultations will hold until the end of FY2000, at which point, the two Governments will decide whether to continue the consultations.

In addition to the Measures which already have been implemented, the Guidelines will be implemented as of November 4, 1994, except for procurements in which a Notice of Procurement or a Request for Comments was published before November 1, 1994. As it is consistent with the Framework, it is confirmed that the benefits of the Measures and Guidelines will be on a Most-Favored-Nation basis.

The Government of Japan will collect the data set forth in Appendix C for use in the consultations described above. Depending on the results of the consultations, the Government of Japan will, if necessary, take appropriate actions, and the Government of the United States will, if necessary, further encourage U.S. firms to take advantage of procurement opportunities created by the Government of Japan and, if appropriate, will consider additional efforts.

With respect to the distribution of direct technology products and services, in accordance with its policy of promoting fair and free competition to increase market entry opportunities, including those of foreign companies, the Government of Japan affirms its commitment to enforce effectively the Anti-Monopoly Act and amend the Guidelines to address anticompetitive activities, if any, related to the distribution of goods and services, including direct technology products and services. The Government of Japan will encourage the private sector, including manufacturers and distributors of direct technology products and services, to establish intra-Anti-Monopoly Act compliance programs.

The Government of Japan recognizes that adequate funding for the procurement of direct technology products and services is a necessary condition for successful procurement. To this end, the Government will request and, as a matter of policy, will maximize efforts in the future to obtain sufficient funds to enable public procurement of direct technology products and services as depicted in the simulation of a procurement in the private sector.

I understand that it is the policy of the Government of the United States to provide non-discriminatory, transparent, fair and open procurement opportunities consistent with its obligations under the GATT Agreement on Government Procurement.

Procurement in conformity in force for the United States the new Agreement on Government Procurement. I
So undersigned the Government of the United States will consult the above-mentioned consultations
with my Government upon requests concerning such policies in areas of particular interest in his sector and
will consider the views of the Government of Japan. The Government of Japan welcomes these policies of the
Government of the United States and implements the Measures and Guidelines in the contents of this letter.

Sincerely

/s/

Takuzo Kuriyama

Ambassador of Japan

The Honorable

Ron H. Brown

Secretary of Commerce

Washington D.C. 20230

Appendix A: Measures Related to Japanese Public Sector Procurement of Medical Technology Products and
Services

Appendix B: Operational Guidelines with Respect to Measures Related to Japanese Public Sector Procurement of
Medical Technology Products and Services

Appendix C: Data Collection

APPENDIX A

MEASURES RELATED TO JAPANESE PUBLIC SECTOR PROCUREMENT

OF MEDICAL TECHNOLOGY PRODUCTS AND SERVICES

I. GENERAL POLICIES

1. The purpose of these Measures Related to Japanese Public Sector Procurement of Medical Technology Products
and Services (hereinafter referred to as the "Measures") is to ensure non-discriminatory transparency for
competitive and open public sector procurement procedures. With the aim of achieving this purpose and
significantly increasing access to sales of competitive foreign medical technology products and medical
technology services (hereinafter referred to as "medical technology products and services") in the Japanese
public sector procurement the Government of Japan (hereinafter referred to as the "Government") will
implement the Measures set out below.

2. The Government reaffirms its obligations to observe the provisions of the existing Agreement on Government
Procurement in support of the new Agreement on Government Procurement which is expected to
come into effect on January 1, 1996. Prior to entry into force for Japan of the new Agreement on Government
Procurement the Measures will be implemented in addition to the requirements of the existing Agreement on
Government Procurement while ensuring consistency with it. After entry into force for Japan of the new
Agreement on Government Procurement the Measures will be implemented in addition to the requirements of the
existing and new Agreements while ensuring consistency with them. (The existing Agreement and the new
Agreement are hereinafter referred to collectively as the "Codes".)

3. The Measures will govern procurement by the entities including all of their hospitals specified in Annexes 1
and 2 (hereinafter referred to collectively as the "entities") of all medical technology products and services of no
less than 100,000 SDRs or the Code threshold whichever is lower by any contractual means such as purchase
lease rental or hire purchase.

II. NATIONAL TREATMENT AND NON-DISCRIMINATION

1. With r e t pr cur ment c v r by th Me sur s, th Gø r nment will cc r t f r i n pr ucts n s r vic s n f r i n suppli rs f such pr ucts n s r vic s, tr tment n l ss f v r bl th n it cc r st :

(1) mestic pr ucts, s r vic s n suppli rs n

(2) pr ucts, s r vic s n suppli rs f ny th r f r i n c untry.

2. With r e t pr cur ment c v r by th Me sur s, th Gø r nment will n t:

(1) tr t l c lly- st blish suppli r l ss f v r bly th n n th r l c lly- st blish suppli r n th b sis f r f f r i n f fili ti n r wn r ship r

(2) iscrimin t inst l c lly- st blish suppli r n th b sis th t th pr ucts r s r vic s ff r by th t suppli r f r th p rticul r pr cur ment r f r i n pr ucts r s r vic s.

III. POLICIES AND PROCEDURES APPLICABLE TO ALL PROCUREMENTS COVERED BY THE MEASURES

1. Futur Pr cur ment Pl ns

Entiti s will invit suppli rs t submit c mments n th f ll win pr cur ment pl ns by publishin in th K np pr cur ment inf rmati n f me ic l t chn l y pr ucts n s r vic s (th n me n r ss f th ntity, subj ct matt r f th pr cur ment such s its n me n v lume, pl nn t f th n tic f pr cur ment), c v r by th Me sur s s rly in th fisc l y r s p ssibl , n will mak th inf rmati n v il bl f r public p r us l t c nt ct p int in th ntity, s pr vi f r i n S cti n VI(I). In th c s th t th n tic f pr cur ment r th R qu st f r C mments s t ut in th sub-p r r ph 5 b l wh s b n publish , ntiti s n n t t k th pr c ur st pr vi inf rmati n s t ut in this p r r ph.

2. G n r l R quir ments

2.1 Wh r n ntity h s r quir ment f r me ic l t chn l y pr uct r s r vic , it will un rt k pr cur ment pl nnin n c n uct mark t r s rch, s n c ss ry, in r r t pr mot c mp titi n t th maximum xt nt p ssibl , n t nsur th t th ntity me ts its n s with th most ppr pri t me ic l t chn l y pr uct r s r vic .

2.2 Inf rmatl n ma v il bl n bu t r qu st t ny suppli rs will b ma v il bl n n n- ; iscrimin t ry b sis. N ntity may pr vi v nc kn wl t ny suppli r, if such kn wl woul iv th t suppli r n v nt v r th r suppli rs, b ut pr -t n r inf rmati n, wh r v il bl , t ny st f pr cur ment, fr m th f r mul ti n f bu t r qu st n th b innin f sp cific ti n v l pment thr u h issu nc f t n r cument ti n t war f c ntr ct. Entiti s will cc r qu l cc ss t ll pr -t n r inf rmati n t ll f r i n n mestic suppli rs n pr vi th m with qu l pp rtuniti s t p rticip t in pr -t n r ctiviti s. N ntity may us inf rmati n th r urin th pr -t n r ph s t xclu ny suppli r.

2.3 Entiti s will nsur th t ll suppli rs r iv n th s me pp rtuniti s t p rticip t in t chnic l r f r nc c mmitt s, vis ry r ups, stu y c uncils, n ny such r ups, if st blish , th t iscuss th t chn l y, bu t, sp cific ti ns, functi ns r ny th r sp ct f pr cur ments f me ic l t chn l y pr ucts n s r vic s.

2.4 Qu lific ti n f Suppli rs

(1) Entiti s, in th pr c ss f qu lifyin suppli rs in t n rin pr c ur , will n t iscrimin t mon f r i n suppli rs r b twen mestic p f r i n suppli rs.

(2); Entiti s will limit ny c n iti ns f r p rticip ti n t th s th t r ss nti l t nsur th suppli r's c p city t fulfill th c ntr ct in qu sti n.

(3) Entiti s will publish nnu lly in th K np n invit ti n t suppli rs t qu lify, which will s t f r th bj ctiv n sp cific qu lific ti n r quir ments f r p rticip ti n in t n rs.

(4) In t rminin wh th r suppli r is qu lifi , ntiti s will c nsi r n t wø rth n busin ss ctiviti s utsi ; f J p n.

(5) Entiti rovid o ortuniti to u i r to qua ify at any time, including aft r a Notic of Procur ment ha b n i u d for a articu ar rocur ment. h qua ification obtain d b ff ctiv unti th n xt r guar qua ification. If qua ifi d at a r guar qua ification, th qua ification b ff ctiv for at a t t y ar .

(6) Entiti notify u i r in iting of th r ut of th qua ification. If th ntity do not qua ify a u i r, th ntity notify th u i r of th r a on for th di qua ification and that it i ntit d to r qu t furth r x ànation thin v n d ày of r c i t of th di qua ification notic .

2.5 Entiti not a rd a contract for medica t chno ogy roduct or rvic to any u i r, or to it affiat , if that u i r ha rovid d r arch or d ign rvic for that rocur ment, and uch invo v ment cou d r ut i h an unfa r comp titiv advantag , xc t to th xt nt uch rvic ar incud d in th contract for rocur ment r quiring th R qu t for Comment roc dur t out in th Mæ ur .

2.6 Entiti tr at fo o on contract a arat rocur ment ubj ct to th roc dur t out in th Mæ ur . Contract a rd d a th r ut of th x rci of o tion or r n rovi ion in a contract a rd d in accordanc th th roc dur t out in th Mæ ur not b con id r d "fo o on" contract . a

2.7 No ntity may:

(1) r ar , d ign or oth r tructur any rocur ment th th int ntion of avoiding th a ication of th Mæ ur or favoring any articu ar u i r; or

(2) divid a rocur ment th th int ntion of r ducing th va u of any r uting contract b o th thr ho d t out in S ction I.

2.8 Entiti :

(1) d t rmi th va u of contract con i t nt th th Cod and th Mæ ur , in d t rmining th r a rocur ment i ubj ct to th Mæ ur .

(2) not ct a va uation method for a ro o d rocur ment th th int ntion of avoiding th h a ication of th Mæ ur .

3. nd ring Proc dur

3.1 Entiti u o n t nd ring roc dur , to th maximum xt nt o ib , for th rocur ment of medica t chno ogy roduct and rvic .

3.2 h Gov rnment n ur that th t nd ring roc dur of it ntiti :

(1) ar a i d in a n n-di criminatory mann r;

(2) do not rovid any u i r th information on a cific rocur ment in a mann r that u d hav th ff ct of dimini hing comp tition; and

(3) ar con i t nt th th rovi ion of th Mæ ur . o

4. Limitation on Sing nd ring

4.1 Entiti r duc th ir u of ing t nd ring.

4.2 B cau i comp titiv rocur ment ar th foundation of th Gov rnment' rocur ment oici and ractic , ing t nd ring b u d on y in xc tion a ca , ju tifi d in accordanc th Cod roc dur , and not b u d to favor or xcud dome tic or for ign u i r of medica t chno ogy roduct or rvic , or to contrav n any rovi ion int nt or ur o of th Mæ ur . i

4.3 Exc t in th ca that no t nd r ar ubmitt d in comp titiv t nd ring or no ucc fu t nd r ar r ubmitt d in th cond t nd ring, or in ca of xtr me urg ncy, ntiti ub i h an announc ment of a ing t nd r rocur ment cov r d by th Mæ ur in th Kan o at a t 40 day b for th contract i a rd d. T h notic contain: i

(1) a description of the outcome, including volume to be issued;

(2) the planned outcome;

(3) the Code justification for the single ending; and

(4) the name of an individual, in the case of discussions on the outcome, have begun with the individual

5 Request for Comments

5.1 Request for submission of materials

For the outcome in which the successful development of a series of actions without requiring the submission of materials from the individual, and the outcome awards of which are expected to be greater than 800,000 SDRs, entities will take the following action: the beginning of the fiscal year as early as possible before the beginning of the fiscal year, except in the case of urgency or in the case of single ending provided for in the Code:

(1) Entities will publish a notice in the Kanon of the request for materials and of the necessary information on the basis of the planned outcome, and provide details of the notice of submission of requests

(2) The notice in the Kanon includes the following:

(a) the name and address of the entity;

(b) subject matter of the outcome (its name

and volume, basis of the planned outcome);

(c) deadline of the submission of the materials; and

(d) notice of a conference for the planned outcome, if such a conference is held

(3) The deadline of (c) above will be, except in the case of urgency, at least 45 days after publication of the Request for submission of materials

(4) Where an entity amends or has additional information on entering an announced outcome set out in (2) above, it will simultaneously provide the amendment to additional information to all individuals who have responded to the Request for submission of materials. If the amendment to additional information is entered on entering the subject matter of the outcome set out in (b) above, entities will allow at least 30 days for individuals to respond and respond to the amendment to information

5.2 Request for Comments on drafts of actions

For (c) outcome of modified products to services or services developed products to services, (c) outcome of all off-the-shelf products to services with a value greater than 800,000 SDRs, or (c) outcome of the outcome for which the entity has a knowledge the need to use the Request for Comments, entities will take the following measures to ensure that the individual submits the comments on drafts of actions received by the entity. In the case of urgency, however, the entity may shorten the period of the extension. The individuals will be able to respond, by announcing the reasons for the extended duration of the notice of the Request for Comments in the Kanon. In the case of emergency with which the entity will not be able to cope by the above extended duration, the entity may omit a whole of the extended period set out below, provided that the entity announces the reasons for the omission in the Notice of Outcome

(1) Entities will publish the notice of the completion of development drafts of actions in the Kanon at least 45 days before the intended date of the Notice of Outcome, and will promptly send a copy of the Request for Comments to the individual

(2) Entities will announce the following in the notice of the completion of development drafts of actions:

(a) subject matter of the outcome (its name and volume); .

(b) the address in which the specification may be obtained ;

(c) the deadline for the submission of comment ;

() the name and address of the entity; and

(e) the date and location of the conference at which the specification is to be held .

(3) The deadline for the submission of comment set out in (c) above will be at least 30 days after the day following the publication of the Request for comment at which the specification is .

(4) When entities recognize the need to improve their specifications announced in the notice the Request for amendment shall allow the comment submitter to make the applicable , the entities will notify all the interested parties that have expressed interest in the procedure. In such a case, the entities will allow sufficient time for the deadline for the submission of comment in the applicable to consider and present the amendment in writing to the publication of the Notice of Procedure.

6. Technical Specification

6.1 Any technical specification proposed by an entity will be, where appropriate:

(1) precise in terms of performance rather than design or descriptive characteristics ; and

(2) based on international standards , where such exist, and the widely based international technical regulations recognize national standards .

6.2 Entities will prepare technical specifications with the minimum detail needed to define the performance criteria. Entities will not equate detailed technical details with the performance criteria.

6.3 Entities will formulate specifications in an impartial manner . Entities will not prepare, adopt or apply any technical specifications with the intent of creating a barrier to any applicable standard or applicable , including foreign applicable . If the procedure will replace or interconnect with an existing system, the specifications will not be designed to preclude competition .

6.4 Entities will not allow any applicable directly involved in the development of specifications in a procedure to participate in the tendering process , except where:

(1) the applicable has provided comment in a previous Request for comment , as provided in Section III(5) and such participation would not be ultimately in an unfair competitive advantage of any applicable ;

(2) the applicable has provided in writing a statement to an entity in preparing or reviewing specifications and the entity has concluded that the process and conduct of it in a fair and impartial manner and has provided the same opportunity to all applicable to provide in writing a statement;

(3) the applicable has provided , at the request of an entity, product specifications that allow a product to be applicable and all applicable to provide an equal and impartial opportunity to participate in providing product specifications that .

6.5 Entities will not provide a technical specification that equates to a trademark or a name, patent, design type, proprietary process or applicable unless the entity in the sufficiently precise intelligible way of describing the procedure equates to a product that, in such a case , would be a " equivalent" as included in the tender documentation .

7. Notice of Procedure

7.1 Entities will invite all applicable to participate in the procedure by publishing in the Kanban Notice of Procedure at least 50 days , in principle, but in no case less than 40 days , prior to the deadline for the submission of tender , unless justified by the entity .

7.2 Each entity will, after publishing the Notice of Procedure in the Kanban , promptly make such Notice available to the public free of charge at a contact point in the entity, as provided in Section VI (1).

7.3 The N e Pr uremen will n lude su en n rma n r a supplier make an n rmed de s n as whe her par pa e n he pr uremen , and will n an he ll wing n rma n:

- (1) su je ma er he pr uremen ;
- (2) me h d evalua n enders;
- (3) he addresses r m wh h he ender d umen a n may e a ned; b
- (4) a pre- ender n eren e s held, s da e and l a n; and
- (5) he deadl ne and address r he su miss n enders.

7.4 I a er pu l a n he N e Pr uremen , u e re he deadl ne r su miss n enders, he en y amends he N e, will pu l sh he amendmen n he Kanp and make he n rma n ava la le r pu l perusal a a n a p n n he en y, as pr v ded r n Se n VI (1).

8. Tender Do umen a n

8.1 En es will use ender d umen a n mmun a e he r needs suppliers and s l enders r m hem.

8.2 En es will prepare he ender d umen a n, n lud ng evalua n r er a when he verall grea es value me h d l gy s used, n an mpar al manner s as ensure ha equal pp r un es are pr v ded all suppliers n a n d s r min a ry ass. b

8.3 In prepar ng ender d umen a n, n en y may a ep he pr v s n any ass s an e r m any supplier, wh h uld g ve ha supplier any advan age ver her suppliers, her han n a rdan e wi h he pr edures se u n he Measures.

8.4 Tender d umen a n pr v ded suppliers will n a n all n rma n ne essary permi hem su mi resp ns ve enders, n lud ng n rma n requ red e pu l shed n he N e Pr uremen , ex ep r he amoun and erms paymen any sum paya le r he ender d umen a n, and he ll wing:

- (1) he address he en y wh h enders sh uld e sen and he names ers resp ns le r he pr uremen ;
- (2) b he address wh h reques r supplemen ary n rma n sh uld e sen ;
- (3) he language r languages n wh h enders and her ender ng d umen s mus e su mi ed;
- (4) he l s ng da e and me r re ep enders and he leng h me dur ng wh h any ender sh uld e pen r a ep an e;
- (5) he pers ns au h rzed e presen a he pen ng enders and he da e, me and pla e he pen ng;
- (6) any e n mi and e hn al requ remen s, nan al guaran ees and her n rma n requ red r m suppliers; b
- (7) a mple e des r p n he pr du s r serv es e pr ured and requ remen s, n lud ng e hn al spe a ns, n rmi y er a n and ne essary plans, drawings and ns ru nal ma er als;
- (8) all r er a ha will e applled de ermine he su ess ul supplier ha will e awarded he n ra , n lud ng all evalua n a rs and su - a rs, we gh ed n erms mp r an e he evalua n and n lud ng any a rs ha are e ns dered and he s elemen s e n luded n evalua ng pr es, su h as ransp r a n, nsuran e and nspe n s s;
- (9) he erms paymen ;
- (10) a pre- ender n eren e s held, s da e, me and l a n; and
- (11) any her erms r nd ns. b

8.5 Entiti

- (1) mak th_i t nd r documentation avai ab at th time of pub ication of th Notic of Procur ment
- (2) nd th t nd r documentation promptly to a uppi r upon it r qu t
- (3) r p y promptly to any r a onab r qu t for information r vant to th t nd r documentation mad by a uppi r participating in th t nd ring proc dur , on th condition that uch information do not giv that uppi r an advantag ov r it comp titor in th a rd of th contract
- (4) promptly put in iting communication th uppi r , xc pt n it impo an unn c ary burd n on th ntity, conc rning th pr paration of t nd r documentation, including p cification , tandard and oth r t nd ring trms. r i ring trms. h

9. Pr -T nd r Conf r nc

9.1 At a t 30 day prior to th d ad in t out in th Not c of Procur ment for th ubmi ion of t nd r , ntiti hod a pr -t nd r conf r nc th r gard to any procur ment for ich R qu t for Comment proc dur ar to b tak n a t out in S ction III (5) and for any oth r procur ment, a n c ary. Such conf r ric includ th opportunity for dir ct di cu ion b t n uppi r^h and that ntity on t chnica , admini trativ and any oth r a p ct of th procur ment, and for a uppi r to obtain information on t nd ring on an qua ba i .

9.2 Entiti not mak att ndanc at a pr -t nd r conf r nc a pr r qui it for t nd r ubmi ion or con id r att ndanc in th va uation of t nd r .

10. Eva uation of T nd r

10.1 In va uating t nd r and cting th ucc fu uppi r, ntiti u a ction proc dur d ign d to

- (1) maximiz comp titio_in
- (2) minimiz th comp xity of th t nd r documentation, th va uation and th ction d ci ion and
- (3) n ur impartia and compr h n iv va uation of t nd r ubmitt d by uppi r .

10.2 Entiti va uat t nd r in a tran par nt mann r that n ur qua tr atment of a uppi r ubmitting t nd r . Wh r an ntity conduct t chnica va uation , it conduct th m und r th ame condition for a uppi r in th t nd ring proc and appy th ame t ting crit ria, ich b mad imm diat y avai ab to uppi r on r qu t.

10.3 No ntity r fu to con id r a ar pon iv t nd r any off r by a uppi r to uppy^h a product that i u d, or acc pt d for u , in any Sp cia Function ho pita or oth r ho pita or aboratory a part of th High y-Advanc d Medica T chno ogy program, if th product me t th p cification t out in th t nd r documentation.

10.4 Entiti va uat t nd r a fo o

- (1) Aft r a on y ar pr paration p ri od fo o ng introduction of th M ea ur , ntiti va uat t nd r and a rd contract ba d on th ov ra gr at t va u for th ntiti , for (i) procur ment of modifi d product or rvic or p cia y d v op d product or i rvic or (ii) procur ment of off-th - h if product or rvic a^ath a va u gr at r than 800,000 SDR . For oth r procur ment , ntiti may u th ov ra gr at t va u methodo ogy ba d on th i r o d ci ion. i
- (2) T nd r b va uat d on a pa /fai ba i ba d upon th p cific t chnica and oth r va uation crit ria tat d in th p cification , and contract b a rd d to th o t-pric d t nd r among tho t nd r ich ; i

have met the evaluation criteria, unless the entity has the overall greatest value methodology as set out in paragraph (1) above.

10.5 Where evaluation factors are decided based on the overall greatest value methodology, the following principles will apply:

(1) entities will evaluate tenders based on overall greatest value of the entity, which is determined by considering financial and performance factors, price and other factors specified in the tender document. Entities will apply the relative weights set out in the tender document to the evaluation criteria. The price/ cost evaluation may be based on the total life cycle cost principle.

(2) entities may require local trials for product types as part of the evaluation process leading to the award of the contract, provided that this requirement is set out in the tender document and the local trials are conducted on a fair and impartial manner.

(3) Where entities use the overall greatest value methodology, they may not have the evaluation factors and their relative importance for a specific requirement with technically amended tender document and provided the amended tender document is the same matter the same suppliers as the original tender document.

(4) Entities will make the award as soon as practicable after completion of the evaluation process.

(5) entities will put writing promptly evaluation factors and the resulting selection decisions, including the scoring of all factors and comments on responses for selection decisions.

10.6 No supplier will be allowed to modify the tender after submission.

11. Contract Award Information

11.1 The entity will make the award as soon as practicable after completion of the evaluation process and will publish information on the contract award. The Kapadipr promptly notify all suppliers that submitted tenders of its selection and the award price, and will also make the information available for public perusal at a date prior to the entity, as provided for in Set VI(I).

11.2 Upon request from a successful supplier, an entity will promptly provide such supplier with an explanation of the reasons for not being selected, the name of the selected supplier and the relative advantages of that supplier's tender where the overall greatest value methodology is used.

11.3 In doing these cases where entities provide information in accordance with paragraph 11.2, entities will do the following:

(1) disclose to any third party a supplier's trade secrets, manufacturing process, intellectual property or other confidential business information provided by a supplier; or

(2) supply to any third party information that would prejudice the legitimate commercial interest of a supplier or unfairly compete among suppliers.

12. Post-Award Contract Modification

A modification of the specified contract that would increase the value of the contract by more than 10 percent of its value will be subject to the provisions of the Measures as if it were a new procurement.

IV. REGULATORY REQUIREMENTS

1. entities will implement restrictions, other than those based on laws and regulations, as a supplier a prerequisite for medical technology products and services for the reason that it is governing the procurement.

2. The Measures are added to, added to, supersede, the measures described in the Market-Ordered, Set of Selective Medical equipment and Pharmaceutical Arrangements for all within measures (hereafter E

referred to collectively as the "MOSS measures"). In the event of conflict between the Measures and the MOSS measures, the MOSS measures will be followed.

V. SUPPORTING MEASURES

1. Improvement of Methods to Provide Procurement Information

Entities will make the maximum possible use of procedures described in 6. of the Procedures for Government Procurement on Products (Operation Guidelines) to contribute to confidence for domestic and foreign suppliers that the expressed interest in government procurement of medical technology products and services.

2. Follow-up of the Measures

To ensure effective implementation of the Measures, the Government will set up a forum for follow-up to examine concrete steps including the following.

2.1 The Government will establish a committee to study standardized manuals to develop non-discriminatory and simplified specifications for procurements of medical technology products and services procured by two or more entities.

2.2 The Government will establish a committee to develop standardized format, consistent with the Measures, to be used by entities, to the extent practicable, for tender document preparation of medical technology products and services.

2.3 Training

The Government will establish a program to provide training for entity procurement officials regarding the implementation of the Measures.

3. Procurement-related Groups

Where the Government establishes a committee or similar groups, whether formal or informal, which includes non-private sector or both public and private sector participation, primarily related to the public sector procurement of medical technology products or services, the Government will publish notice of the KAPO of information related to the group's establishment.

VI. PROVISION OF INFORMATION FOR ALL PROCUREMENTS REGARDLESS OF VALUE

For procurements of medical technology products and services by the entities, without regard to the value of the procurement, the Government will take the following actions:

1. Entities will establish a central contact point to provide information about procurements of medical products and services. The entity, in addition, will provide the information to other appropriate contact points of institutions of the entity.

2. Entities will develop and publish a list of procurement officials responsible for the procurement of medical technology products and services and make it available for public perusal. This contact point in the entity, as provided for in Section VI (1).

3. Each hospital covered by the measures will, on an annual basis, publish the outlook for the volume, or the value where expression of value is not possible, of the top 10 categories of medical technology products and services, both by consumer-based and non-consumer-based, that it expects to procure for that fiscal year, and will make the information available to its contact point, as provided for in Section VI(1). The Government will develop Regulations for categories of specifications to be used for this outlook.

4. Meetings

4.1 Entities will conduct an annual conference for entity procurement officials and domestic and foreign suppliers to discuss information about the entities' major short-term procurement plans and, with budgetary

reservation to either on a long-term procurement outlook. This may be replaced by the entity's participation in a similar cooperative established by the Government or the entities.

4.2 Each entity conducting a procurement cooperative publishes notice of the cooperative in the *Kaipo* at least 30 days prior to the cooperative.

5. The entity:

(1) advise officials involved in the implementation of procurement to meet with domestic and foreign suppliers on request and to be responsive to their questions and concerns; and

(2) ensure that such officials do not provide preferential access to domestic or foreign suppliers.

VII. UNFAIR TENDERS

1. Give that it is the policy of the Government to procure medical technology products and services based on the standards that are consistent with the Anti-Monopoly Act including the prohibition against unjustly priced sales, entities take appropriate action to address anticompetitive practices.

2. Where a supplier submits a tender that because of its price or other terms unfairly impedes fair competition, the entity deems the tender void in its entirety and does not consider that tender in awarding the contract.

3. Entities deem a supplier that submits a tender referred to in paragraph 2 to be eligible to resubmit a tender in the medical technology product or service procurement; and the entities announce the name of that supplier publicly.

4. Where entities obtain information indicating the existence of practices that may impede fair competition in relation to its procurement including the formulation of their procurement specifications, the entities provide such information on a timely basis to the Fair Trade Commission so as to enable the Commission to take such steps as it deems appropriate.

5. To this end, Entities provide the names of their contact persons to the Fair Trade Commission to facilitate procedures for the detection of and exchange of information concerning practices that may violate the Anti-Monopoly Act.

VIII. COMPLAINT MECHANISMS

Procedures of fair competition mechanisms described in Article 4 of the Act on Reform of Bidding and Contracting Procedures for Public Works (hereafter referred to as the "Act on PA") be applied to provide equitable timely transparent and effective competition procedures for suppliers of medical technology products and services covered by the Measures until the Agreement to Government Procurement enters into force and Japan becomes a party to it. The title "contracting procurement review board" be replaced by "procurement review board". In light of the nature of medical technology products and services the foregoing modifications be made. (For ease of reference, Article 4 of the Act on PA as amended by the foregoing is attached as Annex 3 of the Measures.)

1. Replace 2-3-4-(4) and 6-(2) of Article 4 of the Act on PA respectively by 3-1 3-8 3-4 and 5-2 of Article III of the Measures related to Japanese Public Sector Procurement of Computer Products and Services. "Potential suppliers" in Article 4 of the Act on PA be replaced by "suppliers" whereas "commissioning entity" by "entity".

2. Change the duration for making a report (5-() of Article 4 of the Act on PA) to 90 days.

IX. ENCOURAGEMENT TO PREFECTURAL GOVERNMENT AND DESIGNATED CITIES

The Government encourage prefectural governments and Designated Cities to take the principle necessary measures similar to the Measures for their procurement of not less than 200,000 SDRs taking into account local circumstances and the provisions of relevant laws and regulations.

The Government will encourage preferential government-sourced Designated Countries to consider establishing a revenue mechanism to respect her procurement of no less than 200,000 SDRs.

TIME TABLE FOR IMPLEMENTATION

The Measures will be basically reduced to the maximum extent for procurement under the national budget of FY1994, and a system for procurement will be established by the end of FY1994.

I. REVIEW OF THE IMPLEMENTATION OF THE MEASURES

The Government will hold a review to assess the extent to which the Measures contribute to improvement of productivity, spare capacity, openness, competitiveness and fairness of procurement of medical technology products and services covered by the Measures, and, add to, to address specific issues implementing the Measures. The review will be held annually, as necessary, under the Committee for Drafting a Draft Program of the Action Program. Addressing the relationship of the review will be governed by the Cabinet Councilors' Office of External Affairs. A review will be made of the implementation of the Measures will be examined by us as a subject of her relevance for the country. This will include the opportunity of the government to do so and foreign companies and business associations.

II. DEFINITIONS

which

work

For purposes of the Measures:

"Days" means calendar days, except the case of Article 3, here references to days means working days;

"Locally-established supplier" means a supplier has established in Japan, regardless of the source of its capital;

"Medical technology products" means medical instruments, medical apparatus, medical supplies and materials, excluding those for a military use, listed in Annex 1 of the Enforcement Order of the Pharmaceutical Affairs Law

"Medical technology services" means designated services of medical technology products, and designated services of software which solely used medical technology products;

"Supplier" means a person who has provided or could provide products or services in response to a Notice of Procurement;

"Affiliates" means (a) companies which a supplier or has provided research or design services controls or are controlled by, or (b) other companies which are controlled by a company controlling a supplier or has provided research or design services, where control means ownership excess of 50% of the issued stock of the affiliates as a stock corporation, and ownership excess of 50% of the capital of the affiliates as a limited company;

"Modified products or services" means medical technology products or services has existed in the international marketplace at the time the Request for Contents is published in the Kaboku requirement of the Ministry of Health, the legal requirements of the country for the procurement has substantially reformed the functional or essential physical characteristics;

"Off-the-shelf products or services" means medical technology products or services has existed in the international marketplace at the time the Request for Contents or the Notice of Procurement is published in the Kaboku; and

"Specially developed products or services" means medical technology products or services has developed in the international marketplace and has been developed especially on the legal requirements of the country for the procurement.

ANNEX IX

CENTRAL GOVERNMENT ENTITIES

House of Representatives

House of Councilors X

Supreme Court

Chief Justice

Cabinet

Ministry of Personnel and Administration

Prime Minister's Office

Foreign Trade Commission

Ministry of Public Safety Commission

(Ministry of Police Agency)

Environment and Disputes Commissioner in Commission

Imperial Household Agency

Management Commission in Agency

Health Development Agency

Defense Agency

Economic Planning Agency

Science and Technology Agency

Environment Agency

Okinawa Development Agency

Ministry of Labor Agency

Ministry of Justice

Ministry of Foreign Affairs

Ministry of Finance

Ministry of Education

Ministry of Health and Welfare

Ministry of Agriculture, Forestry and Fisheries

Ministry of International Trade and Industry

Ministry of Transport

Ministry of Posts and Telecommunications

Ministry of Labor

Ministry of Consumer Affairs

Ministry of Home Affairs

ANNEX 2

OTHER ENTITIES COVERED BY THE MEASURES

Health Insurance Company

Especially in Railway Company

Central a an a l y Company

West a an a l y Company

Sh koku a l y Company

Kyushu a l y Company

a an Fre ght a l y Company

a an Tobacco Inc

N on Telegra h an Tele hone Cor rat on

Peo le's F nance Cor rat on

Houston Loan Cor rat on

Agr culture, Forestry an F sher es F nance Cor rat on

Small Bus ness F nance Cor rat on

F nance Cor rat on of Local Publ c Enter r se

Hokka o an Tohoku Develo ment Cor rat on

Soc al Welfare an Me cal Serv ces Cor rat on

Small Bus ness Cre t Insurance Cor rat on

Env ronmental San tat on Bus ness F nanc ng Cor rat on

Ok na Develo ment F nance Cor rat on

a an Develo ment Bank

Ex ort-Import Bank of a an

Labour Welfare Cor rat on

ANNEX 3

Procurement ev e Boar

1. Boar

(1) The Boar ll have no substant al nterest n the outcome of a rocurement subject to ts rev e

(2) The Boar ll rece ve compla nts n t ng, con uct nvest gat ons of the facts an make recommen at ons to a ent ty th res ect to any as ect of a rocurement by the ent ty.

(3) The Boar ll be compr se of ersons o have kno e ge an ex er ence relate to ubl c sector rocurement. No member of the Boar ll art c ate n the rev e of a compla nt n ch that member has a confl ct of nterest.

(4) Where necessary, the Boar may hear o n ons from techn cal ex erts o have n e th kno e ge an ex er ences relate to the rocurement subject to ts rev e None of those techn cal ex erts shoul have substant al nterest n the outcome of the rocurement.

2. El g b l ty for Compla nt

A su ller may fle a compla nt th the Boar en t bel eves the rocurement has been carr e out n a manner ncons tent th the ntent or any rov s on of the Measures. It may also fle a compla nt base u on the allegat on that the contract s a r e to a su ller that ha submitte a b n v olat on of the Ant mono oly d

Act. Supp a ncou ag d to k out on n t a y with th nt ty of any a g d ncon t ncy with th Mæ u .

3. Pa t c pant

Th nt ty and upp who d ct conomic nt t woud b ff ct d by th awa d of, o th fa u to awa d, a cont act may pa t c pat n a comp a nt p oc d ng.

4. P ocu ment v w P oc

(1) A upp , that b v a p ocu ment cov d by th Mæ u ha b n ca d out n a mann ncon t nt with th nt nt o any p ov on of th Mæ u , may f a comp a nt n wrt ng with th Boa d, at any t me du h th p ocu ment p oc , but no at than 10 day aft th ba of th comp a nt known o a onaby hou d hav b n known. Th upp wi ubmit a copy of th comp a nt to th nt ty with n 1 wo k ng day of f ng t with th Boa d. (Day wi b con d d ca nda day un oth wi p c f d.)

(2) Th Boa d may c v and con d a comp a nt wh ch not t me y f d, f t f nd that good cau hown.

(3) Th Boa d wi v w a comp a nt with n 7 day of t f ng, and may, n wrt ng and with a on g v n, d m any comp a nt found to b :

(a) Not ubmitt d n a t me y mann ;

(b) not ubj ct to th Mæ u ;

(c) f vo ou o t v a on t fac ;

(d) not ubmitt d by a upp ; o

() oth wi napp op at fo v w by th Boa d.

(4) Wh th Boa d d t min that a comp a nt ha b n f d p op y, t wi not fy n wrt ng a upp with n on wo k ng day of th comp a nt.

(5) Su p n on of Awa d of Cont act o Cont act P fo manc

(a) With n 10 day of th f ng of a p -awa d comp a nt, th Boa d wi p ompt y u a wrtt n qu t fo u p n on of cont act awa d p nd ng out on of th comp a nt.

(b) In th ca of a po t-awa d comp a nt, f d with n 10 day aft th awa d, th Boa d wi p ompt y qu t n wrt ng u p n on of th Cont act P fo manc p nd ng out on of th comp a nt.

(c) Th nt ty wi u p nd th awa d o th p fo manc of th cont act mmed at y aft t c v th Boa d' qu t, un th h ad of th nt ty d t min that u g nt and comp ng c cumstanc do not a ow th nt ty to fo ow th qu t, o that th awa d o th p fo manc of th cont act wi b n th b t nt t of Japan, n wh ch ca h wi mmed at y p ov d wrtt n not f cat on to th Boa d of h d t minat on and th factua c cumstanc on wh ch t ba d.

(6) Inv t gat on

(a) Th Boa d wi conduct an nv t gat on of th comp a nt, wh ch may ncud th f ng of b f , p ad ng and oth documentat on by th comp a nt and nt ty.

(b) Th Boa d may, on th qu t of th comp a nt o th nt ty o on th Boa d' own nt at v , ho d a h a ng on th me t of comp a nt .

(7) po t by th Ent ty

(a) With n 14 day aft th day on wh ch a copy of th comp a nt wa nt to th nt ty, th nt ty wi f with th Boa d a wrtt n po t on th comp a nt, conta ng th fo ow ng:

) vant documentat on fo t nd , ncud ng th p c f cat on o po t on th of vant to th comp a nt; R

ii) all other comments relevant to the complaint;

iii) a statement that sets out all relevant facts, findings, actions and recommendations of the entity and responds fully to all allegations of the complaint;

iv) any additional relevant information that may be necessary in order to solve the complaint.

(b) The Board will, forthwith after giving the appropriate notice to the complainant, send a copy of the relevant material to the complainant and give the complainant an opportunity, within 7 days after it receives the relevant material, to file with the Board comments on the fact that the Board is on the existing record. The Board will, forthwith after giving the comments, send a copy to the entity.

5. Findings and Recommendations

(1) The Board will make a report of its findings and recommendations to the entity within 90 days after the day on which the complaint is filed. Its findings, in which the Board will grant only the complaint in whole or in part, will specify whether the proposed remedy was inconsistent with the intent of specific provisions of the Measures.

(2) When the Board finds evidence of misconduct, actions of bad behavior contrary to law, it will find the matter to be appropriate for remedial action.

(3) In making its findings and recommendations, the Board will consider all the circumstances concerning the proposed remedy, including the seriousness of any finding in the proposed remedy, the degree of prejudice to any of the parties, the degree of impairment to the integrity and

effectiveness of the Measures, the good faith of the participants, the extent of the harm of the conduct to which the proposed remedy relates, the cost of the

recommendation to the Government of Japan, the gravity of the proposed remedy, and the impact of the recommendation on the business of the entity.

(4) When the Board finds that the intent of any provision of the Measures has not been followed, it will recommend an appropriate remedy, including one or more of the following:

(a) that an written recommendation be issued;

(b) that a written report be submitted to the Board;

(c) that the offender be revalued;

(d) that the conduct be awarded to another party;

(e) that the conduct be terminated.

(5) The Board will send its findings in writing with its recommendations to the complainant, the entity and any other participants, within 1 working day after issuance.

(6) The entity will, in principle, and as its own decision, fully follow the findings of the Board on any complaint brought appropriately before the Board. The entity must report to the Board within 60 days of receipt of the Board's recommendation, if it has decided not to comply with the recommendation with the reasons for its decision.

(7) The Board will respond to external inquiries concerning its findings.

6. Expedient Option

(1) When the complainant or the entity consents in writing an expedient handling of a complaint, the Board will consider the feasibility of giving the proposed remedy in this situation, for the "expedient option."

(2) The Board will determine whether to apply the express provision that requiring the receipt of the request of the entity to file the complaint in the entity's file, whether the express provision is to be applied.

() Whether the express provision is applied, the time limits on procedure shall be set forth in this Paragraph.

() The entity will, within six years after the year in which it is notified by the Board that the express provision is to be applied, file with the Board the written report on the complaint, as specified in paragraph 4.(7) above. The Board will, forthwith after receiving the report, send a copy of the relevant material to the complaint entity and the participants. The Board will give the complaint entity and the participants 5 years to file with the Board comments on such material. The request that the case be decided on the existing record. The Board will, forthwith after receiving the comments, send a copy to the entity.

(b) The Board will issue its findings and recommendations on the complaint in writing within 25 years after the year in which the complaint is filed.

7. Document Retention

To contribute to the above purposes, each entity will maintain complete document retention of all procurement not less than the threshold set forth in I.2. of the Measures, for five years from the date of the contract, to allow verification that the procurement process complied with the requirements of the Measures.

(APPENDIX 1) MEDICAL TECHNOLOGY PROCUREMENT PROCEDURES

[The following has not been included in this electronic version. It is available in hard copy.]

Appendix 2

List of Central Contract Points set forth in Section VI of the Measures

Entity Contract Point Tel. Number Ext. Fax Number

House of Representatives

House of Councils Procurement Section Accounts

Div., General Affairs Dept.

Accounts Div., General Affairs Dept. 0 - 581-9111

0 - 581- 1112 2

25790 - 581-9214

0 - 581-1020

Supreme Court

Board of Audit

Cabinet of Prime Minister's Office

Financial Commission Auditing Div., Accounting Bureau

Accounts Div., Secretariat

Contracts Section, Accounts Div., Minister's Secretariat

Personnel Accounts Div., Executive Office Secretariat 0 - 264-8111

0 - 581- 251

0 - 581-2 61 3

03-3581-5471344

8

3

43403-3 34-35

03-3581-807 A

03-3581- 7

03-3581-1 3

tion I Public Safety Commission (tion I Police Agency) A

Environment I Disputes Coordination Commission

Imperial Household AgencyFinance Div., Commissioner, General's Secretariat

ccounts Section, General Affairs Div., Executive Office

Section in Charge of the Acts to Incur Disbursement, cct. Div.03-3581-0141

03-3581- 3 1

03-3 13-1111 43

351 A

7 03-3581-0 33

03-3581- 488

03-3 8 -1541

Management and Coordination AgencyExamination Section, ccounts Div., Director General's Secretariat03-3581-
3 1414803-350 -1 41

Hokkaido Development AgencyFirst Accounting Section, General Affairs Div.03-3581- 111 3 503-3581-1 08

Defence AgencyHealth & Medical Division, Bureau of Education & Training03-3408-5 11 07103-374 -1413

Economic Planning Agency

Science & Technology Agency A

Environment Agency ccounts & Budget Division

Finance Div., Minister's Secretariat

ccounts Section, Budget & ccts. Div., Minister's Secretariat03-3581-0 1

03-3581-5 71

03-3581-33 151

7 A

17003-3581- 404

03-3504- 84

03-35 3-8 3

OkinawaDevelopment Agency ccts. Div., General Affairs Bureau03-3581- 3 140 303-5 51-7177 A

National Agency: Section, Budget & Accounts Div., Minister's Secretariat 03 35 3 3311 15303 3501 534

Ministry of Justice: Utilities Office, Finance Div., Minister's Secretariat 03-3580-4111221203-35 2-7112

Ministry of Foreign Affairs: Procurement Office, Finance

Affairs Div., Minister's Secretariat 03-3580-5257 Internal 03-3581- 444

Entity Contact Point: TEL Number, Ext. Fax Number

Ministry of Finance: First Account Settlement Section, Accounts Div., Minister's Secretariat 03-3581-4111212603- 9 5251-2162

Ministry of Education: Law & Regulation Unit, General Affairs Section, Budget & Accounting Div., Minister's Secretariat 03-3581-4211218503-35 1-8140

Ministry of Health & Welfare

Ministry of Agriculture, Forestry & Fisheries: Accounts Div., Minister's Secretariat

General Section on Specific Procurements, Accounting Div., Minister's Secretariat 03-3503-1711

03-3502-81112212

24 103-3508-1112

03-3506-1 35

Ministry of International Trade & Industry: Budget & Accounts Div., Minister's Secretariat 03-3501-1511223603- 9 3580-24 3

Ministry of Transport: Senior Contract Coordinator Office, Finance Div., Minister's Secretariat 03-3580-3111588503- 9 3580-7804

Ministry of Posts & Telecommunications: International Procurement Planning Office, Finance Dept., Minister's Secretariat 03-3504-4241 Internal 03-3504-01 4

Ministry of Labour: Finance Div., Minister's Secretariat 03-35 3-1211511203-3502-2 50

Ministry of Construction: Procurement Information Section, Finance Dept., Minister's Secretariat 03-3580- 9 4311227703-5251-1 23

Ministry of Home Affairs: Section of Contract & Payment, Finance Div., Minister's Secretariat 03-3581-531142203- 35 7-0065

Hokkaido Railway Company

East Japan Railway Company

Central Japan Railway Company

West Japan Railway Company

Shikoku Railway Company

Kyushu Railway Company

Japan Freight Railway Company: Purchasing & Stores Div., Finance Department

Purchasing & Stores Div., Finance Department

Materials Section, Finance Dept.

Purchasing & Stores Div., Finance Department 9

Purchasing Division, Finance Department
Purchasing Division, Finance and Accounting Department
Purchasing Division, Finance Department 011-222-7131

03-3212-257

052-54-2538

03-375-8991

0878-22-3990

093-331-3504

03-3212-8908direct

direct

direct 6

direct

direct

direct

direct011-21-8146

03-3712-2581

052-54-2535

03-375-882

0878-22-3990

093-331-35046

03-3285-0070

Japan Tobacco Inc. General Administration Division, General Administration Department 03-3474-3111 232203-5479-0340

Nippon Telegraph and Telephone Co., Ltd. International Procurement Office 03-3509-8044direct03-3593-1794

People's Finance Corporation

Housing Loan Corporation

Agriculture, Forestry and Fisheries Finance Corporation

Japan Finance Corporation for Small Business

Finance Corporation of Local Public Enterprise

Hokkaido-Tohoku Development Corporation

Social Welfare Medical Service Corporation

Small Business Credit Insurance Corporation

Environmentally Friendly Business Finance Corporation

Okikawa Development Finance Corporation 6

Japan Development Bank

Export-Import Bank of Japan

Labour Welfare Corporation

Supply Div., General Affairs Dep.

Construction, Accounting Div., Finance & Accounting Dep.

General Affairs Div., General Affairs Department

General Service Div., General Service Department

Second Section, General Affairs Div.

General Service Div., Business Construction & Accounting Dep.

Accounting Section, General Accounting Dep.

Accounting & Treasury Div., Accounting & Treasury Dep.

Accounting Div., Accounting Dep.

General Affairs Div., General Affairs Dep.

General Services Div., General Services Dep.

Planning & Coordination Div., Administration Dep. A

Construction Div., Accounting Dep. 03-3270-4111

03-3796-6111

03-3270-2261

03-3270-1261

03-3581-0311 A

03-3270-1657

03-3438-9929

03-3270-2361

03-3582-5416

03-3581-3241

03-3244-1860

03-3287-9445

03-3292-8871

726

296A

338

2511

30 A

281 A

direct

83 H

direct

direct

direct

direct

3 3 3 9 79

3 3796 6 76

3 3 7 35

3 3 7 7

3 35 6 969

3 3 6 776

3 3 38 9

3 3 3

3 358 73

3 35 8 33

3 3 7 8 97

3 3 87 95

3 3 9 8836^{HN}

APPENDIX B H
HN

[MEDICAL TECHNOLOGY]

OPERATIONAL GUIDELINES WITH RESPECT TO MEASURES RELATED TO JAPANESE PUBLIC SECTOR
PROCUREMENT OF MEDICAL TECHNOLOGY PRODUCTS AND SERVICES

The Government of Japan has decided to issue and implement these Operational Guidelines to supplement and clarify the Measures Related to Japanese Public Sector Procurement of Medical Technology Products and Services (hereinafter referred to as "the Measures") which were decided by the Committee for Drawing Up and Promoting the Action Program on 8th March, 99, as follows. In carrying out the Measures, the Guidelines will be fully implemented and respected.

I. NOTICE

In carrying out the measures, entities recognize that they should meet their needs with the most appropriate competitive medical technology products or services without regard to national origin. To this end, the head of each entity specified in Annexes and of the Measures will send a notice to all procurement officials within his or her authority, including those in hospitals, encouraging them to give fair, non discriminatory and positive consideration in all procurements without regard to the threshold to the procurement of competitive foreign medical technology products and services, with the understanding that such procurements constitute positive and beneficial steps in implementing the Measures. The notice will, in this regard, also ask the hospitals and other subordinate organizations within his or her entity to assist foreign suppliers, on request, in appointments and contacts with procurement officials in those organizations. H

2. SECTION III. FUTURE PROCUREMENT PLAN

When an entity publishes in the Kanpo procurement information on medical technology product and service covered by the Measure set forth in Section III. , the entity will invite supplier to submit material , comment and other necessary information on the procurement. Entity will give full consideration to any information submitted by supplier .

3. SECTION III.5 REQUEST FOR COMMENT

() In the case of Request for Submission of Material set forth in Section III.5. , supplier can submit material and comment on the entity's actual need with regard to the procurement for which a Request for Submission of Material has been issued.

(2) With respect to Section III.5. , all procurement in which the contract award is expected to be greater than 800,000 SDR are deemed to be those in which entities face difficulties in developing appropriate specification without requesting the submission of material from supplier .

(3) For procurement in which the contract award is expected to be 800,000 SDR or below, entities may use the Request for Submission of Material procedure when they determine that they face difficulties in developing appropriate specification without requesting the submission of material from supplier .

(4) The phrase in Section III.5.2 of the measure , which states "entities will take the following measure in order to ensure that interested supplier submit their comment on draft specification prepared by the entity " is not intended to limit comment submitted to those on draft specification . Supplier can submit material and comment on, in addition to draft specification , other technical information or any other aspect of the procurement, including the supplier's view on the estimated cost of the procurement.

4. THRESHOLD FOR THE GREATEST VALUE EVALUATION AND REQUEST FOR COMMENT

() With respect to the threshold that applies to overall greatest value evaluation and Request for Comment , as set out in Section III.5. , III.5.2 and III. 0.4 of the Measure and paragraph 3(2) and 3(3) of the Guideline , the Government will lower the threshold from 800,000 SDR to 600,000 SDR on April , 1996, to 400,000 SDR on April , 1997, and to 385,000 SDR on April , 1998.

(2) Off-the-shelf product or service with a unit value of 500 SDR or below which are being procured in high volume may be exempted from the area to which overall greatest value evaluation and Request for Comment procedure apply.

5. SECTION VI.4 MEETING

Entity which procured in the previous fiscal year a total of two million SDR or more of medical technology product and service covered by the Measure will hold their own meeting .

6. SECTION XII DEFINITIONS

"Medical technology product " include , in addition to those described in Section XII of the Measure , in-vitro diagnostic reagent stipulated in Article 56-2 of the Enforcement Regulation of the Pharmaceutical Affairs Law.

APPENDIX

DATA COLLECTION (MEDICAL TECHNOLOGY)

1. The Government of Japan will report the following information and data annually, beginning with Calendar Year 1994, for procurement subject to the Measure

1. The total number and value of contract awarded by all covered entities and by each such entity

() in the aggregate for each of the four product categories specified in the Annex and each service category; and

(2) in the aggregate for all product ; and

(3) in the Attachment; and

1.2 The total number and value of contracts awarded to or in products and services by the entity and by such entity:

(1) In the Attachment, the product category is specified in the annex and the category;

(2) In the Attachment; and

(3) in the Attachment;

1.3 The number and percentage of contracts that were single and multiple contracts, the value of such contracts, and the number and value of those contracts awarded to or in products and services.

1.4 The total number and value of contracts awarded by the entity and by such entity:

(1) In the case of only the domestic products or services were submitted;

(2) In the case of only the domestic products or services were submitted; and

(3) in the case of both the domestic and domestic products or services were submitted, broken down by contracts awarded to domestic products or services and those awarded to or in products or services.

NOTE The above information by the entity covered by the Measures will most likely fluctuate by year.

II. The Government of Japan will provide the following information and details, in accordance with the Civil and Y 1995, the Diagnostic X-ray apparatus (B2901), the medical diagnostic equipment (B2303), Nuclear medicine sonographic equipment (B2907), the diagnostic equipment (B2701), and the medical equipment (B2701) and the medical equipment (B2701) provided by the entity covered by the Measures by:

2.1 The total value of contracts awarded by the entity and by such entity; and

2.2 The total value of contracts awarded to or in products by the entity and by such entity.

NOTE The above information and details by the entity covered by the Measures will most likely fluctuate by year. The above information by the entity covered by the Measures will most likely fluctuate by year.

The above information by the entity covered by the Measures will most likely fluctuate by year.

NNEX

CATEGORIZATION OF MEDICAL TECHNOLOGY PRODUCTS

1. Medical Technology Products of Diagnosis, which consists of the following:

(a) products and codes B09, B11, B13, B15, B17, B27, B29, B31 and B37 in the Survey of Pharmaceutical Industry Productions, and

(b) in-vitro diagnostic tests.

2. Medical Technology Products of Treatment (except for surgery), which consists of the products and codes 01, 03, 05, B01, B05, B19, B23, B33 and B35 in the Survey of Pharmaceutical Industry Productions.

3. Medical Technology Products of Surgery, which consists of the products and codes B03, B21 and B25 in the Survey of Pharmaceutical Industry Productions.

4. Miscellaneous, which consists of the products and codes 07 (except for Surgical Goods), 09 and B07 in the Survey of Pharmaceutical Industry Productions.

THE SECRETARY OF COMMERCE A

Washington, D.C. 20230

November 1, 1994

His Excellency

Takakazu Kuriyama

Ambassador of Japan

2520 Massachusetts Avenue, N.W.

Washington, D.C.

Dear Ambassador Kuriyama:

I am pleased to receive your letter of today's date concerning procurement of medical technology products and services in the Japanese public sector market and the "Measures Related to Japanese Public Sector Procurement of Medical Technology Products and Services" (hereinafter referred to as the "Measures") and "Operational Guidelines with Respect to Measures Related to Japanese Public Sector Procurement of Medical Technology Products and Services" (hereinafter referred to as the "Guidelines") attached thereto.

The Government of the United States reaffirms the Framework for a New Economic Partnership established by the "Joint Statement on the Japan-United States Framework for a New Economic Partnership" of the Heads of the Governments of Japan and the United States on July 10, 1993 (hereinafter referred to as the "Framework"). The goals of the Framework are to deal with structural and sectoral issues in order substantially to increase access and sales of competitive foreign goods and services through market-opening and macroeconomic measures; to increase investment; to promote international competitiveness; and to enhance bilateral economic cooperation between the United States and Japan.

I am pleased to learn that to accomplish these goals with respect to Japanese public sector procurement of medical technology products and services your Government has adopted the Measures and Guidelines with the aim of significantly increasing access and sales of competitive foreign medical technology products and services in the Japanese public sector procurement market.

I welcome your Government's decision to implement the Measures and Guidelines and willingness to keep the Measures and Guidelines under continual review. I would like to confirm that the Governments of Japan and the United States will meet in June 1995 and annually thereafter to ratify and time up on the request of either Government to discuss any matters related to the Measures and Guidelines including assessment of implementation of the Measures and Guidelines and evaluation of progress achieved toward the goals of the Framework and the goals of this sector as set forth above. I would like to confirm that such consultations will be held until the end of FY2000 at which point the two Governments will decide whether or not to continue these consultations pending on the results of the consultations described above. The Government of the United States will, if necessary, further encourage U.S. firms to take advantage of opportunities created by the Government of Japan and if appropriate consider additional efforts.

Assessment of the implementation of the Measures and Guidelines as well as the evaluation of progress achieved will be based on the overall consideration of the following qualitative and quantitative criteria. These qualitative and quantitative criteria will be considered as a set and none of the criteria will be determinative of the assessment of the Measures and Guidelines or the evaluation of progress achieved. These criteria do not constitute numerical targets but rather are to be used for the purpose of evaluating progress achieved toward the goals of the Framework and the goals of this sector as set forth above.

1. QUANTITATIVE CRITERIA

Annual evaluation of progress in the value and share of procurements of foreign medical technology products and services covered by the Measures and Guidelines to achieve, over the medium term, a significant increase in access and sales of competitive foreign medical technology products and services by:

1.1 Annual alu an ar of procur ment of for ign me ical t c nology pro uct an r ic co r by t Mæ ur an Gui lin , aluat by r f r nc to r c nt tr n in t alu ,rat of growt an ar of procur ment of for ign me ical t c nology pro uct an r ic ,an t total alu of procur ment co r by t Mæ ur an Gui lin ;

NO E In t initial y ar of con ultation (b for multipl y ar of ata a b n coll ct) it will b n c ary to con i r r c nt Kanpo ata.

1.2 Annual numb r of ntiti procur ing for ign me ical t c nology pro uct an r ic co r by t Mæ ur an Gui lin , in r lation to t total numb r of ntiti procur ing me ical t c nology pro uct an r ic co r by t Mæ ur an Gui lin ;

1.3 Annual numb r an alu of contract awar a a r ult of a cr a in ingl t n ring;

1.4 Annual numb r of t n r ubmitt by all uppli r an for ign uppli r ; an

1.5 R lati comp titi n of for ign me ical t c nology pro uct an r ic .

2. QUALI A IVE CRI ERIA

2.1 Full an non- i criminary acc to procur ment information by for ign uppli r at all tag of t procur ment proc , a pro i in t Mæ ur an Gui lin ;

2.2 R ult of t r i wscon uct by t Procur ment R i w Boar ;

2.3 Full impl mentation of all r quir ment of t Mæ ur , Gui lin an l tt r , in a ition to t o mention abo ;

2.4 Effort by for ign uppli r to utiliz procur ment opportuniti , inclu ing comment on raft p cification ; an

2.5 Mark t con ition , inclu ing xc ang rat .

In a ition to t Mæ ur whic alr a y a b n impl ment , t Gui lin will b impl ment a of No mb r 1, 1994, xc pt for procur ment in whic a Notic of Procur ment or a R qu t for Comment wa publi b for No mb r 1, 1994.

I al o wædcome your Go rnment' r affirmation wit r p ct to i tribution of me ical t c nology pro uct an r ic , an op t att maint nanc of t Go rnment of Japan' policy of promoting fair an fr comp titi on will furt r incr a mark t ntry opportuniti T, inclu ing t o of for ign compani . I al o wædcome your Go rnment' ci ion to ncourag t pri at ctor, inclu ing manufactur r an i tributor of me ical t c nology pro uct an r ic , to tabli int rnal Anti-Monopoly Act complianc programs.

I wædcome your Go rnment' int nt to r qu t an , a a matt r of policy, to mak maximum ffort in t futur to obtain uffici nt fun to nabl t public procur ment of me ical t c nology pro uct an r ic ba on pric for imilar pro uct an r ic in imilar working n ironment in t pri at ctor.

I am of t i w t att Mæ ur an Gui lin r pr nt ub tantial progr towar r ol ing probl ms r lat to procur ment by t Go rnment of Japan of me ical t c nology pro uct an r ic an ar a major ac i ment of t Framework. I xp ct t att impl mentation of t Mæ ur an Gui lin will gi for ign me ical t c nology uppli r an r ic pro i r full acc to t public ctor procur ment mark t in Japan. We will continu to monitor t i ituation an , combin wit ffort by U.S. firms, look forwar to incr a acc an al of comp titi me ical t c nology pro uct an r ic by U.S. an ot r for ign firm un r t Mæ ur an Gui lin .

Go rnment of t Unit Stat will ncourag U.S. firms to tak a antag of opportuniti cr at by t Go rnment of Japan. Go rnment of t Unit Stat r confirms t at it i t policy of t Go rnment of t Unit Stat to pro i non- i criminary, tran par nt, fair an op n opportuniti con i t nt wit it obligation un r t GA Agr ment on Go rnment Procur ment an , aft r ntry into forc for t Unit T

States, the e eeme to Gove me t P ocu eme t. My Gove me t ll co sult th you Gove me t
upo equest co ce i such policies, a d a eas of pa ticula i te ests. We a e also p epa ed to p ovide the
Gove me t of Japa th ecessa y i fo matio as equested co ce i bu p ocu eme ts.

Si ce ely,
s

Ro ald H. B o

TANC offers these agreements electronically as a public service for general reference. Every effort has been made to ensure that the text presented is complete and accurate. However, copies needed for legal purposes should be obtained from official archives maintained by the appropriate agency.

/