(MEDICAL TECHNOLOGY)

Dear Secretary Brown:

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

The Government of Japan 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.

To accomplish these goals with respect to Japanese public sector procurement of medical technology products and services, the Government of Japan has adopted the "Measures Related to Japanese 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 Japanese 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 products and services in the Japanese 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.

1.2 Annual number of entities procuring foreign medical technology products and services covered by the Measures and Guidelines, in relation to the total number of entities procuring medical technology products and services covered by the Measures and Guidelines;

1.3 Annual number and value of contracts awarded as a result of a decrease in single tendering;

1.4 Annual number of tenders submitted by all suppliers and foreign suppliers; and

1.5 Relative competitiveness of foreign medical 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 implementation of all requirements of the Measures, Guidelines and letters, in addition to those mentioned above;

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

2.5 Market conditions, including exchange rates.

The Government of Japan will keep the Measures and Guidelines under continual review. The Governments of Japan and the United States will meet in June 1995 and annually thereafter, or at any time upon the request of either Go- eminent, 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 be held until the end of FY2000, at which point, the two Governments will decide whether or not to continue these consultations.

In addition to the Measures which already have been implemented, the Guidelines will be implemented as of November 1, 1994, except for procurements in which a Notice of Procurement or a Request for Comments was published before November 1, 1994. As 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 opportunities created by the Government of Japan and, if appropriate, will consider additional efforts.

With respect to the distribution of medical 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 reaffirms its commitment to enforce effectively the Anti-Monopoly Act and related Guidelines to address anticompetitive activities, if any, related to the distribution of goods and services, including medical technology products and services: The Government of Japan will encourage the private sector, including manufacturers and distributors of medical technology products and services, to establish internal Anti-Monopoly Act compliance programs.

The Government of Japan recognizes that adequate budgets for the procurement of medical technology products and services are necessary to ensure fair and competitive procurements. To this end, my Government will request and, as a matter of policy, make maximum efforts in the future to obtain sufficient funds to enable public procurement of medical technology products and services based on prices for similar products and services in similar working environments 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 opportunities consistent with its obligations under the GATT Agreement on Government Procurement and, after entry into force for the United States, the new Agreement on Government Procurement. I also understand that the Government of the United States will consult, at the above-mentioned consultations, with my Government upon request concerning such policies, and areas of particular interest in this 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 and the contents of this letter.

Sincerely,
/s/
Takakazu Kuriyama

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, transparent, fair, competitive and open public sector procurement procedures. With the aim of achieving this purpose and significantly increasing access and 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 and states its 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 "Code")

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 not less than 100,000 SDRs, or the Code threshold, whichever is lower, by any contractual means, such as purchase, lease, rental and hire purchase.

II. NATIONAL TREATMENT AND NON-DISCRIMINATION

1. With regard to procurement covered by the Measures, the Government will accord to foreign products and services and foreign suppliers of such products and services, treatment no less favorable than it accords to:

   (1) domestic products, services and suppliers; and

   (2) products, services and suppliers of any other foreign country.

2. With regard to procurement covered by the Measures, the Government will not:

(1) treat a locally-established supplier less favorably than another locally-established supplier on the basis of degree of foreign affiliation or ownership; or

(2) discriminate against a locally-established supplier on the basis that the products or services offered by that supplier for the particular procurement are foreign products or services.

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

1. Future Procurement Plans

Entities will invite suppliers to submit comments on the following procurement plans by publishing in the Kanpo procurement information of medical technology products and services (the name and address of the entity, subject matter of the procurement such as its name and volume, planned date of the notice of procurement), covered by the Measures as early in the fiscal year as possible, and will make the information available for public perusal at a contact point in the entity, as provided-for in Section VI(1). In the case that the notice of procurement or the Request for Comments set out in the sub-paragraph 5 below has been published, entities need not take the procedures to provide information set out in this paragraph.

2. General Requirements

2.1 Where an entity has a requirement for a medical technology product or service, it will undertake procurement planning and conduct market research, as necessary, in order to promote competition to the maximum extent possible, and to ensure that the entity meets its needs with the most appropriate medical technology product or service

2.2 Information made available on a budget request to any suppliers will be made available on a non-discriminatory basis. No entity may provide advance knowledge to any supplier, if such knowledge would give that supplier an advantage over other suppliers, about pre-tender information, where available, at any stage of a procurement, from the formulation of a budget request and the beginning of specification development through issuance of tender documentation to award of a contract. Entities will accord equal access to all pre-tender information to all foreign and domestic suppliers and provide them with equal opportunities to participate in pre-tender activities. No entity may use information gathered during the pre-tender phase to exclude any supplier.

2.3 Entities will ensure that all suppliers are given the same opportunities to participate in technical reference committees, advisory groups, study councils, and any such groups, if established, that discuss the technology, budget, specifications, functions or any other aspect of procurements of medical technology products and services.

2.4 Qualification of Suppliers

(1) Entities, in the process of qualifying suppliers in a tendering procedure, will not

discriminate among foreign suppliers or between domestic and foreign suppliers.

(2) Entities will limit any conditions for participation to those that are essential to ensure the supplier's capacity to fulfill the contract in question.

(3) Entities will publish annually in the Kanpo an invitation to suppliers to qualify, which will set forth objective and specific qualification requirements for participation in tenders.

(4) In determining whether a supplier is qualified, entities will consider net worth and business activities outside of Japan.

(5) Entities will provide opportunities to suppliers to qualify at any time, including after a Notice of Procurement has been issued for a particular procurement. The qualification obtained will be effective until the next regular qualification. If qualified at a regular qualification, the qualification will be effective for at least two years.

(6) Entities will notify suppliers in writing of the results of the qualification. If the entity does not qualify a supplier, the entity will notify the supplier of the reasons for the disqualification and that it is entitled to request further explanation within seven days of receipt of the disqualification notice.

2.5 Entities will not award a contract for medical technology products or services to any supplier, or to its affiliates, if that supplier has provided research or design services for that procurement, and such involvement could result in an unfair competitive advantage, except to the extent such, services are included in the contract for procurements requiring the Request for Comments procedures set out in the Measures.

2.6 Entities will treat follow-on contracts as separate procurements subject to the procedures set out in the Measures. Contracts awarded as the result of- the exercise of options or renewal provisions in a contract awarded in accordance with the procedures set out in the Measures will not be considered "follow-on" contracts.

2.7 No entity may:

(1) prepare, design or otherwise structure any procurement with the intention of avoiding the application of the Measures or favoring any particular supplier; or

(2) divide a procurement with the intention of reducing the value of any resulting contracts below the threshold set out in Section I.

2.8 Entities will:

(1) determine the value of contracts consistent with the Code and the Measures, in determining whether a procurement is subject to the Measures.

(2) not select a valuation method for a proposed procurement with the intention of avoiding the application of the Measures.

3. Tendering Procedures

3.1 Entities will use open tendering procedures, to the maximum extent possible, for the procurement of medical technology products and services.

3.2 The Government will ensure that the tendering procedures of its entities:

(1) are applied in a non-discriminatory manner;

(2) do not provide any supplier with information on a specific procurement in a manner that would have the effect of diminishing competition; and

(3) are consistent with the provisions of the Measures.

4. Limitations on Single Tendering

4.1 Entities will reduce their use of single tendering.

4.2 Because competitive procurements are the foundation of the Government's procurement policies and practices, single tendering will be used only in exceptional cases, justified in accordance with Code procedures, and will not be used to favor or exclude domestic or foreign suppliers of medical technology products or services, or to contravene any provision, intent or purpose of the Measures.

4.3 Except in the cases that no tenders are submitted in competitive tendering or no successful tenders are resubmitted in the second tendering, or in cases of extreme urgency, entities will publish an announcement of a single tender procurement covered by the Measures in the Kanpo at least 40 days before the contract is awarded. The notice will contain:

(1) a description of the procurement, including volume to be procured;

(2) the planned contract date;

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

(4) the name of an intended supplier, in the case that discussions on the contract have begun with that supplier.

5. Request for Comments

5.1 Request for submission of materials

For the procurements in which entities face difficulties in developing appropriate specifications without requesting the submission of materials from suppliers, and the contract awards of which are expected to be greater than 800,000SDRs, entities will take the following at the beginning of the fiscal year or as early as possible before the beginning of the fiscal year, except in the case of urgency or in the case of single tendering provided for in the Code:

(1) Entities will publish a notice in the Kanpo of their request for materials and other necessary information on basic needs of the planned procurement, and provide copies of the notice to suppliers upon request.

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

(a) the name and address of the entity;

(b) subject matter of the procurement(its name and volume, basic needs of the planned procurement) ;

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

(d) notice of a conference for the planned procurement, 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 concerning an announced procurement set out in (2) above, it will simultaneously provide the amendment or additional information to all suppliers that have responded to the Request for submission of materials. If the amendment or additional information are concerning the subject matter of the procurement set out in (b)above, entities will allow at least 30 days for suppliers to consider and respond to the amendment or information.

5.2 Request for Comments on draft specifications

For (i) procurements of modified products or services or specially developed products or services, (ii) procurements of all off-the-shelf products or services with a value greater than 800,000 SDRs, or (iii) other procurements for which entities acknowledge the need to use the Request for Comments, entities will take the following measures in order to ensure that interested suppliers submit their comments on draft specifications prepared by the entities. In the case of urgency, however, the entities may shorten the period to the extent that suppliers will be able to respond, by announcing specific reasons for the period reduction in the notice of the Request for Comments in the Kanpo. In the case of extreme urgency with which the entities will not be able to cope by the above period reduction, the entities may omit part or whole of the procedures set out below, provided that the entities announce specific reasons for the omission in the Notice of Procurement.

(1) Entities will publish the notice of the completion of developing draft specifications in the Kanpo at least 45 days before the intended date of the Notice of Procurement, and will promptly send a copy of the Request for Comments to suppliers upon request.

(2) Entities will announce the following in the notice of the completion of developing draft specifications:

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

(b) the addresses from which the draft specifications may be obtained;

(c) the deadline for the submission of comments;

(d) the name and address of the entity; and

(e) the date and location of the conference for draft specifications, if such conference is to be held.

(3) The deadline for the submission of comments set out in (c) above will be at least 30 days after the day following the publications of the Request for Comments for draft specifications.

(4) When entities recognize the need to improve their draft specifications announced in the notice of the Request and amend them as a result of the comments submitted from interested suppliers, the entities will notify all the domestic and foreign suppliers that have expressed interest in the procurement. In such a case, the entities will allow sufficient time for the deadline for the submission of comments in order for suppliers to consider and respond to the amendment or information prior-to publication of the Notice of Procurement.

6. Technical Specifications

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

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

(2) based on international standards, where such exist, and otherwise based on national technical regulations or recognized national standards.

6.2 Entities will prepare technical specifications with the minimum detail needed to define the performance criteria. Entities will not require features not essential to the performance criteria.

6.3 Entities will formulate specifications in an impartial manner. Entities will not prepare, adopt or apply any technical specification with the intent of creating obstacles to any supplier or class of suppliers, including foreign suppliers. If the procurement will replace or interconnect with an existing system, the specifications will not be designed to preclude competition.

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

(1) the supplier has provided comments in response to a Request for Comments, as provided for in Section 111(5) and such participation would not result in an unfair competitive advantage for any supplier;

(2) the supplier has provided information or assistance to an entity in preparing or refining specifications and the entity has controlled the process and conducted it in a fair and impartial manner and has provided the same opportunities to all suppliers to provide information and assistance; or

(3) the supplier has provided, at the request of an entity, product specifications or data about a product it supplies and all suppliers are provided an equal and impartial opportunity to participate or provide product specifications or data.

6.5 Entities will not prescribe a technical specification that requires or refers to a particular trademark or brand name, patent, design or type, specific origin or producer or supplier unless there is no other sufficiently precise or intelligible way of describing the procurement requirements and provided that, in such cases, words such as "or equivalent" are included in the tender documentation.

7. Notice of Procurement

7.1 Entities will invite all suppliers to participate in the procurement by publishing in the Kanpo a Notice of Procurement at least 50 days, in principle, but in no case less than 40 days, prior to the deadline for the submission of tenders, unless justified by the Code.

7.2 Each entity will, after publishing the Notice of Procurement in the Kanpo, promptly make such Notice available for public perusal at a contact point in the entity, as provided for in Section VI(1).

7.3 The Notice of Procurement will include sufficient information for a supplier to make an informed decision as to whether to participate in the procurement, and will contain the following information :

(1) subject matter of the procurement;

(2) method of evaluation of tenders;

(3) the addresses from which the tender documentation may be obtained;

(4) if a pre-tender conference is held, its date and location; and

(5) the deadline and address for the submission of tenders

7.4 If after publication of the Notice of Procurement, but before the deadline for submission of tenders, the entity amends the Notice, it will publish the amendment in the Kanpo and make the information available for public perusal at a contact point in the entity, as provided for in Section VI(l).

8. Tender Documentation

8.1 Entities will use tender documentation to communicate their needs to suppliers and to solicit tenders from them.

8.2 Entities will prepare the tender documentation, including evaluation criteria when the overall greatest value methodology is used, in an impartial manner so as to ensure that equal opportunities are provided to all suppliers on a non-discriminatory basis.

8.3 In preparing tender documentation, no entity may accept the provision of any assistance from any supplier, which could give that supplier any advantage over other suppliers, other than in accordance with the procedures set out in the Measures.

8.4 Tender documentation provided to suppliers will contain all information necessary to permit them to submit responsive tenders, including information required to be published in the Notice of Procurement, except for the amount and terms of payment of any sum payable for the tender documentation, and the following:

(1) the address of the entity to which tenders should be sent and the names of officers responsible for the procurement;

(2) the address to which requests for supplementary information should be sent;

(3) the language or languages in which tenders and other tendering documents must be submitted;

(4) the closing date and time for receipt of tenders and the length of time during which any tender should be open for acceptance;

(5) the persons authorized to be present at the opening of tenders and the date, time and place of the opening;

(6) any economic and technical requirements, financial guarantees and other information required from suppliers;

(7) a complete description of the products or services to be procured and requirements, including technical specifications, conformity certification and necessary plans, drawings and instructional materials;

(8) all criteria that will be applied to determine the successful supplier that will be awarded the contract, including all evaluation factors and sub-factors, weighted in terms of importance to the evaluation and including any factors that are to be considered and the cost elements to be included in evaluating prices, such as transportation, insurance and inspection costs;

(9) the terms of payment;

(10) if a pre-tender conference is held, its date, time and location; and

(11) any other terms or conditions.

8.5 Entities will:

(1) make the tender documentation available at the time of publication of the Notice of Procurement;

(2) send the tender documentation promptly to a supplier upon its request;

(3) reply promptly to any reasonable request for information relevant to the tender documentation made by a supplier participating in the tendering procedures, on the condition that such information does not give that supplier an advantage over its competitors in the award of the contract;

(4) promptly put in writing communications with suppliers, except when it imposes an unnecessary burden on the entity, concerning the preparation of tender documentation, including specifications, standards and other tendering terms.

9. Pre-Tender Conference

9.1 At least 30 days prior to the deadline set out in the Notice of Procurement for the submission of tenders, entities will hold a pre-tender conference with regard to any procurements for which Request for Comments procedures are to be taken as set out in Section 111(5) and for any other procurement, as necessary. Such conferences will include the opportunity for direct discussions between suppliers and that entity on technical, administrative and any other aspect of the procurement, and for all suppliers to obtain information on tendering on an equal basis.

9.2 Entities will not make attendance at a pre-tender conference a pre-requisite for tender submission or consider attendance in the evaluation of tenders.

10. Evaluation of Tenders

10.1 In evaluating tenders and selecting the successful supplier, entities will use a selection procedure designed to:

(1) maximize competition;

(2) minimize the complexity of the tender documentation, the evaluation and the selection decision; and

(3) ensure impartial and comprehensive evaluation of tenders submitted by suppliers.

10.2 Entities will evaluate tenders in a transparent manner that- ensures equal treatment of all suppliers submitting tenders. Where an entity conducts technical evaluations, it will conduct them under the same conditions for all suppliers in the tendering process and will apply the same testing criteria, which will be made immediately available to suppliers on request.

10.3 No entity will refuse to consider as a responsive tender any offer by a supplier to supply a product that is used, or accepted for use, in any Special Function hospital or other hospital or laboratory as part of the Highly-Advanced Medical Technology program, if the product meets the specifications set out in the tender documentation.

10.4 Entities will evaluate tenders as follows:

(1) After a one year preparation period following introduction of the Measures, entities will evaluate tenders and award contracts based on the overall greatest value for the entities, for (i) procurements of modified products or services or specially developed products or services; or (ii) procurements of off-the-shelf products or services with a value greater than 800,000 SDRs. For other procurements, entities may use the overall greatest value methodology based on their own decision.

(2) Tenders will be evaluated on a pass/fail basis based upon the specific technical and other evaluation criteria stated in the specifications, and contracts will be awarded to the lowest-priced tender among those tenders which have met the evaluation criteria, unless the entity chooses the overall greatest value methodology as set out in subparagraph (1) above.

10.5 Where evaluation of tenders is conducted based on the overall greatest value methodology, the following procedures will apply:

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

(2) Entities may require clinical trials of prototypes as part of the evaluation process leading to the award of the contract, provided that this requirement is set out in the tender documentation and the clinical trials are conducted in a fair and impartial manner.

(3) When entities use the overall greatest value methodology, they may not change the evaluation factors and their relative importance for a specific procurement without formally amending the tender documentation and providing the amended tender documentation in the same manner to the same suppliers as the original tender documentation.

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

(5) Entities will put in writing promptly evaluation of tenders and the resulting selection decision, including the scoring of all factors and name of persons responsible for selection decisions.

10.6 No supplier will be allowed to modify the contents of a tender once submitted.

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 in the Kanpo and 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 contact point in the entity, as provided for in Section VI(1).

11.2 Upon request from an unsuccessful 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 Including those cases in which entities provide information in accordance with paragraph 11.2, entities will not:

(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 fair competition among suppliers.

12. Post-Award Contract Modifications

Any modification of the scope of a 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 not impose restrictions, other than those based on laws and regulations, on a supplier in a procurement of medical technology products and services for the reason that it is government procurement.

2. The Measures are in addition to, and do not supersede, the measures described in the Market-Oriented, Sector-Selective Medical Equipment and Pharmaceutical Arrangement or its follow-up measures (hereinafter referred to collectively as the "MOSS measures"). In the event of a 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 (Operational Guidelines) to contribute to convenience for domestic and foreign suppliers that have expressed an 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 forum for follow-up to examine concrete steps including the following.

2.1 The Government will establish a committee to study standardized manual 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 a standardized format, consistent with the Measures, to be used by all entities, to the extent practicable, for tender documentation 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 any committee or similar groups, whether formal or

informal, which includes only 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 in the Kanpo of information related to the group's establishment.

VI. PROVISION OF INFORMATION FOR ALL PROCUREMENTS REGARDLESS OF VALUE

For all 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. Each entity will establish a central contact point to provide information 'about all procurements of medical products and services. The entity, in addition, will provide available information at other appropriate contact points of institutions of the entity.

2. Each entity will develop and publish a list of procurement officials responsible for the procurement of medical techno.1ogy products and services and make it available for public perusal at a 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 by volume is not possible, of the top 10 categories of medical technology products and services, both by consumerables and non-consumerables, that it expects to procure for that fiscal year, and will make the information available at its contact point, as provided for in Section VI(1). The Government will develop guidelines for category classifications to be used for this outlook.

4. Meetings

4.1 Each entity 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 reservations, their longer-term procurement outlook. This may be replaced by the entity's participation in a similar conference established by the Government or their entities.

4.2 Each entity conducting a procurement conference will publish notice of the conference in the Kanpo at least 30 days prior to the conference.

5. The entity will:

   (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. Given that it is the policy of the Government to procure medical technology products and services based on tenders that are consistent with the Anti-Monopoly Act, including the prohibition against unjust low-priced sales, Entities will take appropriate action to address anti-competitive practices.

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

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

4. When 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 will 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 will 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 complaint mechanisms, described in Annex 4 of the Action Plan on Reform of the Bidding and Contracting Procedures for Public Works (hereinafter referred to as the "Action Plan"), will be applied to provide equitable, timely, transparent and effective complaint procedures for suppliers of medical technology products and services covered by the Measures, until the new Agreement on Government Procurement enters into force and Japan becomes a party to it. The title "construction procurement review board" will be replaced by "procurement review board". In light with the nature of medical technology products and services, the following modifications will be made. (For ease of reference, Annex 4 of the Action Plan, as amended by the following, is attached as Annex 3 of the Measures)

1. Replace 2, 3, 4-(4) and 6-(2) of Annex 4 of the Action Plan respectively by 3-1, 3-8, 3-4 and 5-2 of Annex III of the Measures related to Japanese Public Sector Procurements of Computer Products and Services. "Potential suppliers" in Annex 4 of the Action Plan will be replaced by "suppliers", whereas "commissioning entity" by "entity".

2. Change the duration for making a report (5-(l) of Annex 4 of the Action Plan) to 90 days.

IX. ENCOURAGEMENT TO PREFECTURAL GOVERNMENT AND DESIGNATED

CITIES

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

The Government will encourage prefectural governments and Designated Cities to consider establishing a review mechanism with respect to their procurement of not less than 200,000 SDKs.

X. TIME TABLE FOR IMPLEMENTATION

The Measures will be basically introduced to the maximum extent for procurement under the initial budget of FY1994, and a system for procurement in accordance with the Measures will be established by the end of FY1994.

XI. REVIEW OF THE IMPLEMENTATION OF THE MEASURES

The Government will hold a review to assess the extent that the Measures contribute to improvement of non-discriminatory nature, transparency, openness, competitiveness and fairness of procurement of medical technology products and services covered by the Measures and, in addition, to address specific issues in implementing the Measures. The review will be held annually, and as necessary, under the Committee for Drawing up and Promoting the Action Program, Administration relating to the review will be governed by the Cabinet Councillors' Office on External Affairs. At the review, implementation and utilization by suppliers of the Measures will be examined by using statistics and other relevant information. This will include the opportunity of listening to opinions of domestic and foreign companies and business associations.

XII. DEFINITIONS

For purposes of the Measures:

"Days" mean calendar days, except in the case of Annex 3, where references to days means working days;

"Locally-established supplier" means a supplier that is established in Japan, without regard to the source of its capital;

"Medical technology products" means medical instruments and apparatus, medical supplies and dental materials, excluding these for animal use, listed in Annex 1 of the Enforcement Ordinance of the Pharmaceutical Affairs Law;

"Medical technology services" means design services of medical technology products, and design services of software which is solely used in medical technology products;

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

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

"Modified products or services" means medical technology products or services that exist in the international marketplace at the time the Request for Comments is published in the Kanpo but require modification to meet the legitimate requirements of the entity for the procurement that substantially transform their function or essential physical characteristic;

"Off-the-shelf-products or services" means medical technology products or services that exist in the international marketplace at the time the Request for Comments or the Notice of Procurement is published in the Kanpo; and

"Specially developed products or services" means medical technology products or services that do not exist in a form that meets the performance requirements in the international marketplace and must be developed especially to meet the legitimate requirements of the entity for the procurement.

ANNEX 1

CENTRAL GOVERNMENT ENTITIES

House of Representatives
House of Councillors
Supreme Court
Board of Audit
Cabinet
National Personnel Authority
Prime Minister's Office
Fair Trade Commission
National Public Safety Commission
(National Police Agency)
Environmental Disputes Co-ordination Commission
Imperial Household Agency
Management and Co-ordination Agency
Hokkaido Development Agency
Defense Agency
Economic Planning Agency
Science and Technology Agency
Environment Agency
Okinawa Development Agency
National Land 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 Labour
Ministry of Construction
Ministry of Home Affairs

ANNEX 2

OTHER ENTITIES COVERED BY THE MEASURES

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
Japan Tobacco Inc.
Nippon Telegraph and Telephone Corporation
People's Finance Corporation
Housing Loan Corporation
Agriculture, Forestry and Fisheries Finance Corporation
Small Business Finance Corporation
Finance Corporation of Local Public Enterprise
Hokkaido and Tohoku Development Corporation
Social Welfare and Medical Services Corporation
Small Business Credit Insurance Corporation
Environmental Sanitation Business Financing Corporation
Okinawa Development Finance Corporation
Japan Development Bank
Export-Import Bank of Japan
Labour Welfare Corporation

ANNEX 3

Procurement Review Board

1. Board

(1) The Board will have no substantial interest in the outcome of a procurement subject to its review.

(2) The Board will receive complaints in writing, conduct investigations of the facts and make recommendations to a entity with respect to any aspect of a procurement by the entity.

(3) The Board will be comprised of persons who have knowledge and experience related 'to public sector procurement. No member of the Board will participate in the review of a complaint in which that member has a conflict of interest.

(4) Where necessary, the Board may hear opinions from technical experts who have in depth knowledge and experiences related to the procurement subject to its review. None of those technical experts should have substantial interest in the outcome of the procurement.

2. Eligibility for Complaint

A supplier may file a complaint with the Board when it believes the procurement has been carried out in a manner inconsistent with the intent or any provision of the Measures. It may also file a complaint based upon the allegation that the contract was awarded to a supplier that had submitted a bid in violation of the Antimonopoly Act. Suppliers are encouraged to seek resolution initially with the entity of any alleged inconsistency with the Measures.

3. Participants

The entity and suppliers whose direct economic interest would be effected by the award of, or the failure to award, a contract may participate in a complaint proceeding.

4. Procurement Review Process

(1) A supplier that believes a procurement covered by the Measures has been carried out in a manner inconsistent with the intent or any provision of the Measures, may file a complaint in writing with the Board, at any time during the procurement process, but no later than 10 days after the basis of the complaint is known or reasonably should have been known. The supplier will submit a copy of the complaint to the entity within 1 working day of filing it with the Board. (Days will be considered calendar days unless otherwise specified.)

(2) The Board may receive and consider a complaint which is not timely filed, if it finds

that good cause is shown.

(3) The Board will review a complaint within 7 days of its filing, and may, in writing and with reasons given, dismiss any complaint found to be:

(a) not submitted in a timely manner;

(b) not subject to the Measures;

(c) frivolous or trivial on its face;

(d) not submitted by a supplier; or

(e) otherwise inappropriate for review by the Board.

(4) Where the Board determines that a complaint has been filed properly, it will notify in writing all suppliers within one working day of the complaint.

(5) Suspension of Award of Contract or Contract Performance

(a) Within 10 days of the filing of a pre-award complaint, the Board will promptly issue a written request for suspension of contract award pending resolution of the complaint.

(b) In the case of a post-award complaint, filed within 10 days after the award, the Board will promptly request in writing suspension of the Contract Performance pending resolution of the complaint.

(c) The entity will suspend the award or the performance of the contract immediately after it receives the Board's request, unless the head of the entity determines that urgent and compelling circumstances do not allow the entity to follow the request, or that the award or the performance of the contract will be in the best interests of Japan, in which case he will immediately provide written notification to the Board of his determination and the factual circumstances on which it is based.

(6) Investigation

(a) The Board will conduct an investigation of the complaint, which may include the filing of briefs, pleadings and other documentation by the complainant and entity.

(b) The Board may, on the request of the complainant or the entity or on the Board's own initiative, hold a hearing on the merits of complaints

(7) Report by the Entity

(a) Within 14 days after the day on which a copy of the complaint was sent to the entity, the entity will file with the Board a written report on the complaint, containing the following:

i) relevant documentation for tender, including the specifications or portions thereof relevant to the complaint;

ii) all other documents 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 evidence or information that may be necessary in order to resolve the complaint.

(b) The Board will, forthwith after receiving the report referred to in Paragraph (a) above, 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 or request that the case be decided on the existing record. The Board will, forthwith after receiving 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 or deny the complaint in whole or in part, will specify whether the procurement process or award was inconsistent with the intent or specific provisions of the Measures.

(2) Whenever the Board finds evidence of misconduct, actions or behavior contrary to law, it will refer the matter to the appropriate enforcement authorities for action.

(3) In making its findings and recommendations, the Board will consider all the circumstances surrounding the procurement process or award, including -the seriousness of any deficiency in the procurement process, the degree of prejudice to any or all suppliers, the degree of impediment to the integrity and effectiveness of the Measures, the good faith of the participants, the extent of performance of the contract to which the procurement relates, the cost of the recommendation to the Government of Japan, the urgency of the procurement, and the impact of the recommendation on the business of the entity.

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

following:

(a) that a new tender documentation be issued;

(b) that new offers for the contract be sought;

(c) that the offers be re-evaluated;

(d) that the contract be awarded to another supplier;

(e) that the contract 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, duly 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. Express Option

(1) Where the complainant or the entity requests in writing an expeditious handling of a complaint, the Board will consider the feasibility of using the procedure set out in this section, referred to herein as the "express option. "

(2) The Board will determine whether to apply the express option within two working days after receiving a request therefore and will notify the complainant and entity as to whether the express option is to be applied.

(3) Where the express option is applied, the time limits and procedures will be as set forth in this Paragraph.

(a) The entity will, within six days after the day on which it is notified by the Board that the express option is to be applied, file with the Board a 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 complainant and any other participants. The Board will give the complainant and any other participants 5 days to file with the Board comments on such material or 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 days after the day on which the complaint is filed.

7. Document Retention

To contribute to the above procedures, each entity will maintain complete documentation related to all procurement not less than the thresholds set forth in 1.2. of the Measures, for five years from the date of the contract award, to allow verification that the procurement process was carried out in accordance with the Measures.

APPENDIX B

[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 28th March, 1994, as follows. In carrying out the Measures, the Guidelines will be fully implemented and respected.

1. 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 1 and 2 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.

2. SECTION III. l: FUTURE PROCUREMENT PLANS

When an entity publishes in the Kanpo procurement information on medical technology products and services covered by the Measures as set forth in Section III.l, the entity will invite suppliers to submit materials, comments and other necessary information on the procurement. Entities will give full consideration' to any information submitted by suppliers.

3. SECTION III. 5: REQUEST FOR COMMENTS

(1) In the case of Request for Submission of Materials set forth in Section III. 5. 1, suppliers can submit materials and comments on the entity's actual needs with regard to the procurement for which a Request for Submission of Materials has been issued.

(2) With respect to Section 111.5.1, all procurements in which the contract award is expected to be greater than 800,000 SDKs are deemed to be those in which entities face difficulties in developing appropriate specifications without requesting the submission of materials from suppliers.

(3) For procurements in which the contract award is expected to be 800,000 SDKs or below, entities may use the Request for Submission of Materials procedures when they determine that they face difficulties in developing appropriate specifications without requesting the submission of materials from suppliers.

(4) The phrase in Section III. 5.2 of the Measures, which states "entities will take the following measures in order to ensure that interested suppliers submit their comments on draft specifications prepared by the entities" is not intended to limit comments submitted to those on draft specifications. Suppliers can submit materials and comments on, in addition to draft specifications, 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 OVERALL GREATEST VALUE EVALUATION AND REQUEST FOR COMMENTS

(1) With respect to the threshold that applies to overall greatest value evaluation and Request for Comments, as set out in Sections III.5.1, III.5.2 and 111:10.4 of the Measures and paragraphs 3(2) and 3(3) of these Guidelines, the Government will lower the threshold from 800,000 SDRs to 600,000 SDRs on April 1, 1996, to 400,000 SDRs on April 1, 1997, and to 385,000 SDRs on April 1, 1998.

(2) Off-the-shelf products or services with a unit value of 500 SDKs or below which are being procured in high volume may be exempted from the areas to -which overall greatest value evaluation and Request for Comments procedures apply.

5. SECTION VI. 4: MEETING

Entities which procured in the previous fiscal year a total of two million SDKs or more of medical technology products and services covered by the Measures will hold their own meetings.

6. SECTION XII: DEFINITIONS

"Medical technology products" includes, in addition to those described in Section XII of the Measures, in-vitro diagnostic reagents stipulated in Article 56-2 of the Enforcement Regulations of the Pharmaceutical Affairs Law.

APPENDIX C

LATA COLLECTION
(MEDICAL TECHNOLOGY)

I. The Government of Japan will report the following information and data annually, beginning with Calendar Year 1994, for procurements subject to the Measures:

1.1 The total number and value of contracts awarded by all covered entities and by each such entity:

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

(2) in the aggregate for all products; and

(3) in the aggregate for all services;

1.2 The total number and value of contracts awarded for foreign products and services by all covered entities and by each such entity:

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

(2) in the aggregate for all products; and

(3) in the aggregate for all services;

1.3 The number and percentage of contracts that were single tender contracts, the value of such contracts, and the number and value of those contracts awarded for foreign products and services.

1.4 The total number and value of contracts awarded by all covered entities and by each such entity:

(1) in the cases that only tenders of domestic products or services were submitted;

(2) in the cases that only tenders of foreign products or services' were submitted; and

(3) in the cases that both tenders of domestic and foreign products or services were submitted, broken down by contracts awarded for domestic products or services and those awarded for foreign products or services.

NOTE: The above-referenced data by each entity covered by the Measures will most likely f luctuate year by year.

II. The Government of Japan will report the following information and data annually,

beginning with Calendar Year 1995, for Diagnostic X-ray apparatus (B2901), Artificial cardiac pacemakers (B2303), Nuclear magnetic resonance CT equipment (B2907) , Testing apparatus for clinical chemistry (B2701), and Artificial joints and bones (A0105) procured by the entities covered by the Measures by:

2.1 The total value of contracts awarded by all entities and by each entity; and

2.2 The total value of con-tracts awarded for foreign products by all entities and by each entity.

NOTE: Alphabet and Number in parentheses are the code used for categorization in the Survey of Phamaceutical Industry Productions. Since the above-referenced data are for several selective categories of medical technology products, it does not necessarily reflect the general situation of all government procurement of medical technology products. The above-referenced data by each category will most likely fluctuate year by year.

ANNEX

CATEGORIZATION OF MEDICAL TECHNOLOGY PRODUCTS

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

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

   (b) in-vitro diagnostic reagents.

2. Medical Technology Products for Treatments (except for Surgery), which consists of the products under codes A01, A03, A05, B01, BOS, B19, B23, B33 and B35 in the Survey of Pharmaceutical Industry Productions.

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

4. Miscellaneous, which consists of the products under codes A07 (except for Sanitary Goods), A09 and B07 in the Survey of Pharmaceutical Industry Productions.

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, 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. 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. Depending 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 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.

1.2 Annual number of entities procuring foreign medical technology products and services covered by the Measures and Guidelines, in relation to the total number of entities procuring medical technology products and services covered by the Measures and Guidelines;

1.3 Annual number and value of contracts awarded as a result of a decrease in single tendering;

1.4 Annual number of tenders submitted by all suppliers and foreign suppliers; and

1.5 Relative competitiveness of foreign medical 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 implementation of all requirements of the Measures, Guidelines and letters, in addition to those mentioned above;

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

2.5 Market conditions, including exchange rates.

In addition to the Measures which already have been implemented, the Guidelines will be implemented as of November 1, 1994, except for procurements in which a Notice of Procurement or a Request for Comments was published before November 1, 1994.

I also welcome your Government's reaffirmation with respect to distribution of medical technology products and services, and hope that the maintenance of the Government of Japan's policy of promoting fair and free competition will further increase market entry opportunities, including those of foreign companies. I also welcome your Government's decision to encourage the private sector, including manufacturers and distributors of medical technology products and services, to establish internal Anti-Monopoly Act compliance programs.

I welcome your Government's intent to request and, as a matter of policy, to make maximum efforts in the future to obtain sufficient funds to enable the public procurement of medical technology products and services based on prices for similar products and services in similar working environments in the private sector.

I am of the view that the Measures and Guidelines represent substantial progress toward resolving problems related to procurements by the Government of Japan of medical technology products and services and are a major achievement of the Framework. I expect that the implementation of the Measures and Guidelines will give foreign medical technology suppliers and service providers full access to the public sector procurement market in Japan. We will continue to monitor this situation and, combined with efforts by U.S. firms, look forward to increased access and sales of competitive medical technology products and services by U.S. and other foreign firms under the Measures and Guidelines.

The Government of the United States will encourage U.S. firms to take advantage of opportunities created by the Government of Japan. The Government of the United States reconfirms that it is the policy of the Government of the United States to provide nondiscriminatory, transparent, fair and open opportunities consistent with its obligations under the GATT Agreement on Government Procurement and, after entry into force for the United States, the new Agreement on Government Procurement. My Government will consult with your Government upon request concerning such policies, and areas of particular interest. We are also prepared to provide the Government of Japan with necessary information as requested concerning our procurements.

Sincerely,
Ronald H. Brown