Voluntary Conformity Assessment System Evaluation (NVCASE) Program. ANSI believes NVCASE has potential to promote U.S. products' access to foreign markets when foreign governments insist on U.S. government assurance that U.S. conformity assessment organizations are competent to satisfy the foreign regulatory requirements. NIST recognition of ANSI's accreditation service for certification programs and the ANSI-RAB American National Accreditation Program for Registrars of Quality Systems could, for example, help in the situation where the European Commission requests a government assurance of the competence of conformity assessment organizations who desire to participate in government to government Mutual Recognition Agreements. The ANSI and ANSI-RAB national accreditation programs are based on the same technical criteria that generally appear in the European directives relating to competence of notified bodies appointed by Member States

ANSI, RAB and the private sector have invested heavily in establishing the ANSI and ANSI-RAB accreditation programs to respond to marketplace needs. The essence of both accreditation programs is an initial and on-going assessment of the competence of a conformity assessment activity to international criteria in order to promote U.S. national and global marketplace acceptance of the work of the accredited conformity assessment activities. Through bilateral, regional and international discussions with counterpart national accreditation practices and an internationally-based system for global acceptance of product certifications and quality system registrations. NVCASE recognition will nicely complement these ongoing private sector initiatives when a foreign government insists on U.S. government involvement in the process

There, please consider this as a formal request under Section 286,7 for *recognition* of the ANSI Accreditation Program for Certification and the ANSI-RAB American National Accreditation Program for Registrars of Quality Systems. If NVCASE is not yet accepting applications for recognition, then please consider this a notice of intention to seek such recognition, and please send whatever forms are necessary as soon as they are available. Please let us know the fees to be submitted under Section 286.7(a)(2). Also, can you estimate the remaining balance to secure recognition?

Please send as soon as possible the "documented generic requirements to be applied in evaluations related to accreditation and recognition within the scope of the program," mentioned in Section 286.5. Sections 286.5 and 286.6 state that "generic requirements are developed with public input, and "input is also sought from workshops." To the extent that such generic requirements are still in development, ANSI and RAB offer whatever assistance you may find helpful in organizing workshops or other means to facilitate "public input." We were very pleased to see the discussion

We were very pleased to see the discussion in the preamble relating to the purpose of NVCASE to limit NVCASE to only those procedures necessary to meet foreign governments' requirements (Section 286.1).

NVCASE "recognition" procedures should not exceed that required by the foreign government. As a generalization, the criteria for competence of European notified bodies as contained in the European directives are the same criteria used in the ANSI and ANSI-RAB accreditation programs. There may be only small variations needed in our accreditation programs depending upon any unique competence criteria identified in a particular European directive. The European directives place the obligation on Member States to name only "competent" notified bodies. The Member States often (though this is not a requirement) depend upon their relevant national accreditation system for an independent assessment of that competence. We see NVCASE essentially creating a similar relationship between our accreditation programs and the U.S. government. Based on our interactions with European national accreditation organizations through the European Accreditation of Certification (EAC) and International Accreditation Forum (IAF) we have learned that the national accreditation organizations' relationships with their respective governments are best described as cooperative or collaborative. In some cases the accreditation body is an agency of government. In other cases it is a quasi nongovernmental organization whose recommendations result in a government accreditation. In some cases it is a private sector organization whose accreditations are unilaterally considered by government in appointments of notified bodies. In all cases of which we are aware, the accreditation program derives (or derived during its initial stages) significant public sector funding. Thus, we request that you give strong consideration in the NVCASE procedures applicable to recognizing such accreditation programs as ours to the cooperative and facilitate relationships that exist between the European national accreditation programs and their corresponding governments. Our European accreditation counterparts are not faced with a "regulatory" relationship with their governments, but instead one in which the governments just utilize (to a greater or lesser extent in any particular Member State) the results of the accreditation in their appointment of notified bodies

We in the United States could undermine our competitive position internationally rather than advance it if the NVCASE recognition procedures for our accreditation programs generated significant additional costs for our national accreditation programs that will have to be born by the accredited organizations and their U.S. industrial clients. Our accreditation peers in Europe have received government subsidies for the equivalent accreditation service. Significant extra costs for NVCASE recognition would just exacerbate this competitive issue for U.S. conformity assessment programs.

ANSI and RAB intend to offer the ANSI and the ANSI–RAB accreditation programs as a generic mechanism that could be used as the competence demonstrating component in any particular government to government negotiation of Mutual Recognition Agreements. Thus, we were grateful to note that the NVCASE programs would only operate at the accreditation level if (among several conditions) there is no satisfactory accreditation alternative available and the private sector has declined to make acceptable accreditation available (Section 286.2(2)). Our programs are striving to fill this need for an acceptable private sector accreditation mechanism and we envision few, if any situations that could not be addressed by our programs. For NVCASE to offer an accreditation program competing with our private sector efforts would be inappropriate and inconsistent with the concepts in OMB Circular A76 relating to government use of commercially available services

ANSI and RAB look forward to a close and cooperative working relationship with NIST in pursuing our common objective of assisting U.S. suppliers in meeting foreign technical regulatory requirements on a cost effective basis.

Sincerely,

George T. Willingmyre, P.E.,

Vice President, Washington Operations.

cc: S. Mazza

ANSI Board Committee on Conformity Assessment

G. Lofgren, RAB

October 21, 1994.

John Donaldson,

Chief, Standards Code and Information, National Institute of Standards & Technology, Building 101, Room A–629, Gaithersburg, MD 20899

Dear John: This is an addendum to our May 10 formal application for recognition of the ANSI Accreditation Program for Certification Programs and the ANSI-RAB American National Accreditation Program for Registrars of Quality Systems under the National Voluntary Conformity Assessment System Evaluation (NVCASE) program. Our original application is included for reference as Appendix A.

You indicated in your July 12 letter (Appendix B) that we should identify the foreign regulations for which our accreditation programs seek recognition. Based upon interest from currently accredited quality system registrars and product certification programs and industry sectors with high priority for on-going government to government mutual recognition agreement negotiations, the list of European Directives and foreign regulations is provided at Appendix C. Please note that our accreditation programs are designed to mirror the national accreditation programs in Europe and Mexico which use generic criteria to establish the competence of quality system registration or product certification programs no matter what the industry sector. Thus we would expect that NVCASE recognition granted for one program area could be easily extended to other areas without major extra effort or cost.

You also noted that International Guides relevant to competence of quality system registration and product certification accreditation programs are not yet final. Because of the importance of moving forward quickly in the interest of continued American competitiveness, ANSI recommends