27 July 2011

TO: Federal Trade Commission, Office of the Secretary

Gentlemen:

The Association for the Advancement of Medical Instrumentation (AAMI) appreciates the opportunity to provide input in response to FR Doc No: 2011-11704, Request for comments and announcement of workshop on standards-setting issues.

Mission and Background: AAMI provides global leadership and programs to help support the health care community in the development, management and use of safe and effective technology. One of AAMI's primary program areas is standards development for medical technology and related processes.

Throughout its history, AAMI has had a key role in the evolution of the regulation of medical devices, the emergence of the biomedical equipment technician and clinical engineering professions, and the creation of consensus standards and educational programs that have taken on global importance in the production and use of safe and effective medical devices. AAMI has accomplished all of this by serving as a convener of diverse groups of committed professionals from the healthcare community with one common goal – to improve patient outcomes. "Healthcare community" includes the medical device industry, hospitals and other healthcare delivery organizations, government, policy makers, healthcare consultants, clinical care providers, and medical technology professionals, all of whom are part of the AAMI membership. As a multi-disciplinary, 3(c) not-for-profit association, AAMI does not engage in any type of lobbying activity. Our main programs are publications and educational events, standards development, and certification of biomedical equipment technicians.

AAMI Standards Program: The AAMI Standards Program is accredited by the American National Standards Institute (ANSI) and excluding amendments, has 124 current American National Standards and 40 technical information reports (TIRs), including 14 TIRs registered with ANSI. In addition, excluding revisions and amendments, we are currently working on an additional 55 new standards and TIRs. AAMI has been writing standards since it was organized over 40 years ago and many of our documents are in fourth or fifth editions.

AAMI is also involved in international standards development, serving (on behalf of ANSI or its US National Committee to the IEC) as international secretariat of two International Electrotechnical Commission (IEC) subcommittees and four International Organization for Standardization (ISO) technical committees or subcommittees. AAMI also serves as U.S. TAG administrator for one IEC and nine ISO technical committees or subcommittees. One of the goals of our membership is to achieve a single global standard and test for medical devices whenever possible and a majority of AAMI standards and TIRs (64%) are identical national adoptions of ISO and IEC standards.

On average, the national and international committees we are responsible for complete 52 documents per year averaging 45 pages per document. Twenty-five of our current standards are between 100 and 450 pages long. Average development time for our standards is 3 to 4 years, although 5 to 6 years is not atypical and some projects have taken as long as 12 years to complete.

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive Suite 301
Arlington, VA 22203-1633
T +1-703-525-4890 F +1-703-276-0793
www.aami.org

Disclosure of Patent Rights in a Standards-Setting Organization (SSO)

1. How do patent disclosure policies vary among SSOs? How do disclosure policies vary in their effectiveness of making SSO members aware of relevant patent rights?

   Our patent policy is to follow whatever the current ANSI patent policy is. Since we adopt a significant number of international standards, we are also directly impacted by the ISO/IEC patent policy. Copies of both policies are attached (Attachment 1).

   AAMI standards staff is made up of procedural experts, not technical experts, and provides significant support to committees by attending all meetings, providing procedural advice at and between meetings, and handling all distribution of documentation. The two most senior staff members in the department have been with the association for over 20 years during which time we have been involved in completion of around 500 technical documents.

   AAMI standards activity has traditionally focused on safety and performance of medical devices and one of the underlying tenets of our standards philosophy is to avoid design requirements “whenever possible.” As a result, patent issues do not come up often in our standards work. During the last 20 years, staff can recall patent issues coming up only three or four times. In all cases, the fact that a standard might involve patent issues was identified by a committee member.

   Occasionally, it is not possible to avoid design requirements. For example, through joint work between ISO and IEC we are currently developing a series of standards for small bore connectors. The purpose of the standards is to reduce the possibility of accidentally connecting two devices together that are not intended to be connected to one another, which can result in serious patient injury or death. To achieve this goal, design standards for connectors used in different, discrete medical applications are being developed that are not interchangeable. This work is ongoing and we do not yet know whether the committees involved in developing the standards will develop new designs or decide to rely on existing, patented designs for some or all of the applications. In either case, the general standard allows companies to develop their own unique designs provided that design cannot connect to a standardized design.

   In another case, an AAMI technical committee was trying to develop a test method which required use of a patient simulator. One of the companies on the committee had a patent on a suitable simulator and agreed to the AAMI patent policy. That policy specified that the patent holder must provide a letter to the SSO assuring it would make licenses available either without compensation, or under RAND. The company specified in its letter to AAMI that it was willing to “offer licenses without compensation to applicants desiring to utilize the patented technology for the purpose of implementing the standard. The license would be a standard non-exclusive license with a requirement that the licensee fully indemnify and hold harmless [the patent holder] from any and all actions arising out of use of the patented technology.” AAMI, in turn, agreed to include a note in the final standard to indicate that the simulator was patented and who to contact to enter into a license agreement. We should note that the patented item and related test method were not the subject of the standard – the test method was for internal company use to determine whether the company met the requirements in the standard, and the patented technology was not something that would be incorporated into devices that were the subject of the standard. Ultimately, before finalizing the standard the committee decided to instead adopt an international standard which used a different test apparatus, although this was not a significant issue in the committee’s decision to stop work on its own standard and to instead adopt the international standard.

In a third case, after we had completed a standard that provides a system for categorizing hospital gowns and drapes by their barrier properties, we were informed by one member company that another member company was in the process of patenting the classification system. The company abandoned its effort once we contacted them and informed them that the classification system had been developed by one of our committees, and that this "collective work" went back several years culminating in the approval and publication of our standard. So far as we were able to determine, although the company had been involved in the development of the standard, the person representing the company on the committee was not aware until we contacted him that someone else in his company had initiated action to patent the classification system. Apparently, the person suggesting the company patent the classification system was not aware of the source – he had just been given the details of what to implement and thought it was something developed internally and worth patenting.

In a fourth, quite recent case, one of our company members called us for advice. He had been contacted by representatives of an international technical committee that neither his company, nor our association, is involved with. The committee wanted to include something patented by the company in its standard and was seeking the company's permission under ISO/IEC procedures to do so. The company did not wish to license its patent and contacted us to determine who it should write to concerning the matter.

From the above, we would have to conclude that even though patent issues are extremely rare with the types of standards that we develop, our committee members seem to know what the policy is, bring matters to the attention of staff when appropriate during the development of a standard, and at least some of the industry members are already monitoring patent applications from other companies. In short, committee members are in a much better position than AAMI staff to determine whether there is something being proposed for inclusion in a standard under development that is or could be patented, as well as monitoring and bringing to staff's attention new patent applications that could affect an existing standard.

A sea-change in healthcare that is still playing out is the whole area of health IT, "healthcare informatics," eHealth, etc. To date, our work on health IT has been limited to safety and performance issues that might arise from connecting medical devices to one another or to a hospital network. However, there are numerous other traditional standards developers as well as consortia that that are working on standardized protocols, terminology and the like to enable transmission of data between devices, between a device and an electronic patient record, or between two facilities. It should be noted that in the medical device arena, "safety" encompasses a number of things including, for example, security and accuracy of data that is produced by a device, since that data may be used to determine appropriate treatment, with or without physician intervention. As devices become more and more integrated with one another and with hospital IT systems, we expect the healthcare community to identify new, associated risks and our involvement in health IT to grow. This in turn could increase the frequency of essential patent claims related to our standards work.

2. What considerations drive variation in disclosure policies? Why do SSOs adopt policies that may lead to incomplete disclosure of relevant patents, for instance by excluding patent applications from disclosure or by not requiring members to search their patent portfolios?

   Since patent issues come up so infrequently, the current policy is adequate to the task. In addition, requiring members to search their patent portfolios would not capture patents

by companies not on the committee. Lastly, we are not in a position to police whether or not a member did the required search. Having a policy that cannot be monitored and enforced is ineffective.

3. When SSO policies create a potential for incomplete disclosure of members' patent rights, how else can members protect themselves against hold-up?

   While documents are being developed, the committee can always decide to seek an alternative rather than including something that is patented/patentable. As noted previously, committee members are in the best position to know whether something that has been proposed for insertion in a standard is patented, or might be patented either now or at some time in the future (i.e., is "patentable"). Also, at least some of our members have systems in place to monitor patents and patent applications that could affect their product lines. That said, if deemed necessary by the committee, we would consider doing a patent search on request.

   If it came to light after a standard was finalized that the document made reference to an essential patent and the necessary letter had not been sought regarding willingness to license, the committee, any member of the committee, or any other party affected by the standard could:

   - request administrative withdrawal on the basis that AAMI procedures had been violated, and/or
   - the committee could revise or amend the document to remove the patented item from the standard.

   As part of the decision process, staff would investigate the history of the patent application to determine whether there was any possibility that it was based on the committee's work rather than being unique to the patent holder. Depending on what we discovered, legal counsel or staff would contact the patent holder about withdrawing the patent, or providing the necessary letter regarding willingness to license the patent to individuals or companies attempting to implement the standard.

4. When have SSO patent disclosure policies been reviewed or amended? What prompted those reviews? What were the results of the reviews?

   We model our policy after the ANSI patent policy and so it is amended whenever ANSI amends its policy. In the event patent issues became more frequent in our work, we would review the policy to ensure it provided adequate protection to users of our standards as well as to the association.

5. Are there mechanisms for an SSO to encourage disclosure of relevant patents or patent applications held by nonmembers?

   Having a patent policy in one's procedures and distributing same to all committee members, combined with strong staff support/monitoring of committee activities are the main mechanisms available with respect to members. We can't think of any mechanisms available to us to encourage nonmembers to disclose relevant patents (or for nonmembers to be aware that a standard was being developed that included reference to something they had patented) other than to contact a patent holder at the request of a committee to determine whether they would be willing to submit the required letter regarding willingness to license without compensation or under RAND.

6. What ambiguities concerning the scope of a disclosure requirement exist in SSO disclosure policies? Why do they persist? Would more clarity be beneficial in preventing patent hold-up?

   We do not consider our policy ambiguous.

7. What principles apply in judging whether a patent holder's conduct before an SSO is deceptive? What is the role of the SSO's patent disclosure policy in judging whether conduct is deceptive or unfair?

   In our opinion, it is a reasonable assumption on the part of the membership of a standards committee as well as the SSO that whatever members “contribute” to a standard is freely given to the collective work and is not patented, in the process of being patented, nor will the contributor attempt to patent it later unless the member discloses at the time he/she suggests inclusion that one of those situations applies.

   In the case of individuals who are providing directed input, the same would hold if the individual was not aware of a patent issue but others involved in developing company positions on a standard were aware of essential patent issues. (Similarly, when a member volunteers to write a section of a standard or contributes material to a standard via the comment process, the burden is and must be on the member to contribute original work or to inform the SSO that some of his/her contribution is copyrighted and to disclose the source of the material so that the SSO can seek permission from the copyright holder to reproduce the material in its standard.)

   The second part of the question seems to be a legal question.

8. Does non-disclosure or lack of information about relevant patent rights subvert the competitive process of selecting technologies for standards or undermine the integrity of standard-setting activities? How?

   Theoretically, it could in the short term although as noted previously, standards can be withdrawn, revised or amended to deal with non-disclosure situations. This has not been an issue in our 40+ years as an SSO.

The RAND Licensing Commitment. Our common answer to the ten questions under this section is as follows:

> We do not see any role for SSOs in negotiating license agreements between a patent holder and one or more other parties that wish to enter into a license agreement with the patent holder, policing the terms of those agreements, or settling disputes between the patent holder and parties that have entered into or wish to enter into a license agreement with the patent holder. These are private negotiations and contracts between private parties and we have neither the practical nor legal means to monitor, police or enforce these agreements.

Ex Ante Disclosure and/or Negotiation of Licensing Terms. We have no experience with this.

Conclusion: As a relatively small not-for-profit association (total of 35 staff members) that depends on outside legal counsel for the occasional times when legal situations arise, we would find it extremely burdensome, cost prohibitive and ineffective if we were required to do a patent search for every standard that we worked on. Given that these issues rarely come up with the types of standards that we develop, the relatively large number of projects we are involved with, the fact that the content of the drafts as these projects go through the various stages of

standards development can change often and significantly, and our lack of in-house legal staff, we would be hard-pressed to take on this responsibility as a routine matter.

Furthermore, in our experience, committee members are in the best position to know whether something proposed for inclusion in a standard is patented, or might be patented either now or at some time in the future (i.e., is "patentable"), and at least some of our members have systems in place to monitor patents and patent applications that could affect their products and related standards. While we would not want to be required to do a patent search on every standard we develop, we would certainly consider doing a patent search at the request of one of our committees if they were concerned that something they were including in a standard might be patented or in the process of being patented.

Standards are collective works contributed to be numerous volunteers and public reviewers. Even if an SSO had no patent policy, it only stands to reason that material suggested for inclusion is being "freely contributed" unless the person proposing the text discloses at the time that patents or copyrights are involved. Other than taking away their membership or withdrawing/revising the standard, there is little SSOs can do to someone who knowingly failed to disclose patent issues during the development of a standard. Government is in a better position to exact consequences sufficient to deter such deceptive practices.

While we are not experts on patent law, we presume that the decision to grant or not grant a patent is based on whether the concept being patented is unique and original. If technology is already defined in a draft or final standard, that fact should have an impact on the patent office's decision if someone applied for a patent – either on purpose or coincidentally – on the same or very similar technology. Standards developers (at least those accredited by ANSI) retain all committee documentation related to the development and approval of a standard at least until the document is superseded or withdrawn. Therefore, evidence should be available, if needed, regarding when the committee first started discussing the affected parts of their standard.

Many if not most SSOs are not-for-profit associations that typically develop standards to serve a "higher purpose." AAMI, for example, copyrights and sells its standards in order to derive some income to help offset the cost of development. However, we keep our prices low to maximize the distribution and use of our standards because this helps support our overall mission of contributing to patient safety. Even if we had a valid claim, we would not want to start patenting technology that a committee described in one of our standards because this could discourage use of our standards.

Similarly, small SSOs such as ours have no practical means to police RAND agreements, and no SSO has legal authority to enforce such agreements. Disputes between patent holders and licensees are private matters between the parties involved and while some SSOs may be in a position and willing to arbitrate or take legal action on behalf of their members, that certainly should not be a requirement of all SSOs. Most SSOs are small, not-for-profit organizations with significantly less resources than either of the parties involved in such disputes.

Thank you again for the opportunity to comment. Please do not hesitate to contact us if you require any further information.

Sincerely,

Mary Logan, JD, CAE
President

Excerpted from "ANSI Essential Requirements: Due process requirements for American National Standards, January 2009 edition

3.1 ANSI patent policy - Inclusion of Patents in American National Standards

There is no objection in principle to drafting an American National Standard (ANS) in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

If an ANSI-Accredited Standards Developer (ASD) receives a notice that a proposed ANS or an approved ANS may require the use of such a patent claim, the procedures in this clause shall be followed.

3.1.1 Statement from patent holder

The ASD shall receive from the patent holder or a party authorized to make assurances on its behalf, in written or electronic form, either:

a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or

b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:

i) under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
ii) without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

3.1.2 Record of statement

A record of the patent holder's statement shall be retained in the files of both the ASD and ANSI.

3.1.3 Notice

When the ASD receives from a patent holder the assurance set forth in 3.1.1.b above, the standard shall include a note substantially as follows:

> NOTE – The user's attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.
>
> By publication of this standard, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. If a patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then details may be obtained from the standards developer.

3.1.4 Responsibility for identifying patents

Neither the ASD nor ANSI is responsible for identifying patents for which a license may be required by an American National Standard or for conducting inquiries into the legal validity or scope of those patents that are brought to their attention.

3.2 Commercial terms and conditions

Provisions involving business relations between buyer and seller such as guarantees, warranties, and other commercial terms and conditions shall not be included in an American National Standard. The appearance that a standard endorses any particular products, services or companies must be avoided. Therefore, it generally is not acceptable to include manufacturer lists, service provider lists, or similar material in the text of a standard or in an annex (or the equivalent). Where a sole source exists for essential equipment, materials or services necessary to comply with or to determine compliance with the standard, it is permissible to supply the name and address of the source in a footnote or informative annex as long as the words “or the equivalent” are added to the reference. In connection with standards that relate to the determination of whether products or services conform to one or more standards, the process or criteria for determining conformity can be standardized as long as the description of the process or criteria is limited to technical and engineering concerns and does not include what would otherwise be a commercial term.

Excerpted from "ISO/IEC Directives, Part 1: Procedures for the technical work, 2011 edition

ISO/IEC Directives, Part 1

2.14 Reference to patented items (see also Annex I.)

2.14.1 If, in exceptional situations, technical reasons justify such a step, there is no objection in principle to preparing an International Standard in terms which include the use of items covered by patent rights – defined as patents, utility models and other statutory rights based on inventions, including any published applications for any of the foregoing – even if the terms of the standard are such that there are no alternative means of compliance. The rules given below and in the ISO/IEC Directives, Part 2, 2011, Annex F shall be applied.

2.14.2 If technical reasons justify the preparation of a document in terms which include the use of items covered by patent rights, the following procedures shall be complied with:

a) The originator of a proposal for a document shall draw the attention of the committee to any patent rights of which the originator is aware and considers to cover any item of the proposal. Any party involved in the preparation of a document shall draw the attention of the committee to any patent rights of which it becomes aware during any stage in the development of the document.

b) If the proposal is accepted on technical grounds, the originator shall ask any holder of such identified patent rights for a statement that the holder would be willing to negotiate worldwide licences under his rights with applicants throughout the world on reasonable and non-discriminatory terms and conditions. Such negotiations are left to the parties concerned and are performed outside ISO and/or IEC. A record of the right holder's statement shall be placed in the registry of the ISO Central Secretariat or IEC Central Office as appropriate, and shall be referred to in the introduction to the relevant document [see ISO/IEC Directives, Part 2, 2011, F.3]. If the right holder does not provide such a statement, the committee concerned shall not proceed with inclusion of an item covered by a patent right in the document without authorization from ISO Council or IEC Council Board as appropriate.

c) A document shall not be published until the statements of the holders of all identified patent rights have been received, unless the council board concerned gives authorization.

2.14.3 Should it be revealed after publication of a document that licences under patent rights, which appear to cover items included in the document, cannot be obtained under reasonable and non-discriminatory terms and conditions, the document shall be referred back to the relevant committee for further consideration.

Annex I
(normative)
Guidelines for Implementation of the Common Patent Policy for ITU-T/ITU-R/ISO/IEC

(1 March 2007)

Part I – Common guidelines

1 Purpose

ITU, in its Telecommunication Standardization Sector (ITU-T) and its Radiocommunication Sector (ITU-R), ISO and IEC have had patent policies for many years, the purpose being to provide in simple words practical guidance to the participants in their Technical Bodies in case patent rights matters arise.

Considering that the technical experts are normally not familiar with the complex issue of patent law, the Common Patent Policy for ITU-T/ITU-R/ISO/IEC (hereafter referred to as the "Patent Policy") was drafted in its operative part as a checklist, covering the three different cases which may arise if a Recommendation | Deliverable requires licences for Patents to be practiced or implemented, fully or partly.

The Guidelines for Implementation of the Common Patent Policy for ITU-T/ITU-R/ISO/IEC (hereafter referred to as the "Guidelines") are intended to clarify and facilitate implementation of the Patent Policy, a copy of which can be found in Appendix I and also on the web site of each Organization.

The Patent Policy encourages the early disclosure and identification of Patents that may relate to Recommendations | Deliverables under development. In doing so, greater efficiency in standards development is possible and potential patent rights problems can be avoided.

The Organizations should not be involved in evaluating patent relevance or essentiality with regards to Recommendations | Deliverables, interfere with licensing negotiations, or engage in settling disputes on Patents; this should be left - as in the past - to the parties concerned.

Organization-specific provisions are contained in Part II of this document. However, it is understood that those Organization-specific provisions shall contradict neither the Patent Policy nor the Guidelines.

2 Explanation of terms

Contribution: Any document submitted for consideration by a Technical Body.

Free of charge: The words "free of charge" do not mean that the Patent Holder is waiving all of its rights with respect to the essential patent. Rather, "free of charge" refers to the issue of monetary compensation; *i.e.*, that the Patent Holder will not seek any monetary compensation as part of the licensing arrangement (whether such compensation is called a royalty, a one-time licensing fee, etc.). However, while the Patent Holder in this situation is committing to not charging any monetary amount, the Patent Holder is still entitled to require that the implementer of the above document sign a license agreement that contains other reasonable terms and conditions such as those relating to governing law, field of use, reciprocity, warranties, etc.

Organizations: ITU, ISO and IEC.

Patents: Patents refer to essential patents or similar rights, utility models and other statutory rights based on inventions, including any applications for any of the foregoing.

Patent Holder: Person or entity that owns, controls and/or has the ability to license Patents.

Reciprocity: As used herein, the word "reciprocity" means that the Patent Holder shall only be required to license any prospective licensee if such prospective licensee will commit to license its essential patent(s) or essential patent claim(s) for implementation of the same above document free of charge or under reasonable terms and conditions.

Recommendations | Deliverables: ITU-T and ITU-R Recommendations are referred to as "Recommendations", ISO deliverables and IEC deliverables are referred to as "Deliverables". The various types of Recommendation(s) | Deliverable(s) are referred to as "Document types" in the Patent Statement and Licensing Declaration Form (hereafter referred to as "Declaration Form") attached as Appendix II.

Technical Bodies: Study Groups, any subordinate groups and other groups of ITU-T and ITU-R and technical committees, subcommittees and working groups in ISO and IEC.

3 Patent disclosure

As mandated by the Patent Policy in its paragraph 1, any party participating in the work of the Organizations should, from the outset, draw their attention to any known patent or to any known pending patent application, either their own or of other organizations.

In this context, the words "from the outset" imply that such information should be disclosed as early as possible during the development of the Recommendation | Deliverable. This might not be possible when the first draft text appears since at this time, the text might be still too vague or subject to subsequent major modifications. Moreover, that information should be provided in good faith and on a best effort basis, but there is no requirement for patent searches.

In addition to the above, any party not participating in Technical Bodies may draw the attention of the Organizations to any known Patent, either their own and/or of any third-party.

When disclosing their own Patents, Patent Holders have to use the Patent Statement and Licensing Declaration Form (referred to as the "Declaration Form") as stated in Clause 4 of these Guidelines.

Any communication drawing the attention to any third-party Patent should be addressed to the concerned Organization(s) in writing. The potential Patent Holder will then be requested by the relevant Organization(s) to submit a Declaration Form.

The Patent Policy and these Guidelines also apply to any Patent disclosed or drawn to the attention of the Organizations subsequent to the approval of a Recommendation | Deliverable.

Whether the identification of the Patent took place before or after the approval of the Recommendation | Deliverable, if the Patent Holder is unwilling to license under 2.1 or 2.2 of the Patent Policy, the Organizations will promptly advise the Technical Bodies responsible for the affected Recommendation | Deliverable so that appropriate action can be taken. Such action will include, but may not be limited to, a review of the Recommendation | Deliverable or its draft in order to remove the potential conflict or to further examine and clarify the technical considerations causing the conflict.

4 Patent Statement and Licensing Declaration Form

4.1 The purpose of the Declaration Form

To provide clear information in the Patent Information databases of each Organization, Patent Holders have to use the Declaration Form, which is available on the web site of each Organization (the Declaration Form is included in Appendix II for information purposes). They must be sent to the Organizations for the attention, for ITU, of the Directors of the TSB or the BR or, for ISO/IEC, of the CEOs. The purpose of the Declaration Form is to ensure a standardized submission to the respective Organizations of the declarations being made by Patent Holders and, most importantly, to require in the case of ITU, and to strongly desire in the case of ISO and IEC, supporting information and an explanation if a Patent Holder declares his/her unwillingness to license under option 1 or 2 of the Declaration Form (i.e., declares option 3 of the Declaration Form).

The Declaration Form gives Patent Holders the means of making a licensing declaration relative to rights in Patents required for implementation of a specific Recommendation | Deliverable. Specifically, by submitting this Declaration Form the submitting party declares its willingness/unwillingness to license, according to the Patent Policy, Patents held by it and whose licence would be required to practice or implement part(s) or all of a specific Recommendation | Deliverable.

The statement contained in the Declaration Form remains in force as long as it has not been replaced, e.g., in case of obvious errors.

Multiple Declaration Forms are appropriate if the Patent Holder has identified several Patents and classifies them in different options of the Declaration Form and/or if the Patent Holder classifies different claims of a complex patent in different options of the Declaration Form.

4.2 Contact information

In completing Declaration Forms, attention should be given to supplying contact information that will remain valid over time. Where possible, the “Name and Department” and e-mail address should be generic. Also it is preferable, where possible, that parties, particularly multinational organizations, indicate the same contact point on all Declaration Forms submitted.

With a view to maintaining up-to-date information in the Patent Information database of each Organization, it is requested that the Organizations be informed of any change or corrections to the Declaration Form submitted in the past, especially with regard to the contact person.

5 Conduct of meetings

Early disclosure of Patents contributes to the efficiency of the process by which Recommendations | Deliverables are established. Therefore, each Technical Body, in the course of the development of a proposed Recommendation | Deliverable, will request the disclosure of any known Patents essential to the proposed Recommendation | Deliverable.

Chairmen of Technical Bodies will, if appropriate, ask, at an appropriate time in each meeting, whether anyone has knowledge of Patents, the use of which may be required to practice or implement the Recommendation | Deliverable being considered. The fact that the question was asked shall be recorded in the meeting report, along with any affirmative responses.

As long as the Organization concerned has received no indication of a Patent Holder selecting 2.3 of the Patent Policy, the Recommendation | Deliverable may be approved using the appropriate and respective rules of the Organization concerned. It is expected that discussions in Technical Bodies will include consideration of including patented material in a Recommendation | Deliverable, however the Technical Bodies may not take position regarding the essentiality, scope, validity or specific licensing terms of any claimed Patents.

6 Patent Information database

In order to facilitate both the standards-making process and the application of Recommendations | Deliverables, each Organization makes available to the public a Patent Information database composed of information that was communicated to the Organizations by the means of Declaration Forms. The Patent Information database may contain information on specific Patents, or may contain no such information but rather a statement about compliance with the Patent Policy for a particular Recommendation | Deliverable.

The Patent Information databases are not certified to be either accurate or complete, but only reflect the information that has been communicated to the Organizations. As such, the Patent Information databases may be viewed as simply raising a flag to alert users that they may wish to contact the entities who have communicated Declaration Forms to the Organizations

in order to determine if patent licenses must be obtained for use or implementation of a particular Recommendation | Deliverable.

Part II – Organization-specific provisions

Specific provisions for ITU

ITU-1 General Patent Statement and Licensing Declaration Form

Anyone may submit a General Patent Statement and Licensing Declaration Form which is available on the web sites of ITU-T and ITU-R (the form in Appendix III is included for information purposes). The purpose of this form is to give Patent Holders the voluntary option of making a general licensing declaration relative to material protected by Patents contained in any of their Contributions. Specifically, by submitting its form, the submitting party declares its willingness to license all Patents owned by it in case part(s) or all of any proposals contained in its Contributions submitted to the Organization are included in Recommendation(s) and the included part(s) contain items that have been patented or for which patent applications have been filed and whose licence would be required to practice or implement Recommendation(s).

The General Patent Statement and Licensing Declaration Form is not a replacement for the “individual” (see Clause 4 of Part I) Declaration Form, which is made per Recommendation, but is expected to improve responsiveness and early disclosure of the Patent Holder’s compliance with the Patent Policy.

The General Patent Statement and Licensing Declaration remains in force as long as it has not been replaced. It can be overruled by the “individual” (per Recommendation) Declaration Form from the same Patent Holder for any particular Recommendation (expectation is that this will rarely occur).

The ITU Patent Information database also contains a record of General Patent Statement and Licensing Declarations.

ITU-2 Notification

A text shall be added to the cover sheets of all new and revised ITU-T and ITU-R Recommendations, where appropriate, urging users to consult the ITU Patent Information database. The wording is:

“ITU draws attention to the possibility that the practice or implementation of this Recommendation may involve the use of a claimed Intellectual Property Right. ITU takes no position concerning the evidence, validity or applicability of claimed Intellectual Property Rights, whether asserted by ITU members or others outside of the Recommendation development process.

As of the date of approval of this Recommendation, ITU [had/had not] received notice of intellectual property, protected by patents, which may be required to implement this Recommendation. However, implementers are cautioned that this may not represent the latest information and are therefore strongly urged to consult the ITU Patent Information database.”

Specific provisions for ISO and IEC

ISO/IEC-1 Consultations on draft Deliverables

All drafts submitted for comment shall include on the cover page the following text:

> "Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation."

ISO/IEC-2 Notification

A published document for which no patent rights are identified during the preparation thereof, shall contain the following notice in the foreword:

> "Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO [and/or] IEC shall not be held responsible for identifying any or all such patent rights."

A published document for which patent rights have been identified during the preparation thereof, shall include the following notice in the introduction:

> "The International Organization for Standardization (ISO) [and/or] International Electrotechnical Commission (IEC) draws attention to the fact that it is claimed that compliance with this document may involve the use of a patent concerning (...subject matter...) given in (...subclause...).[7]
>
> ISO [and/or] IEC take[s] no position concerning the evidence, validity and scope of this patent right.
>
> The holder of this patent right has assured the ISO [and/or] IEC that he/she is willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statement of the holder of this patent right is registered with ISO [and/or] IEC. Information may be obtained from:
>
> name of holder of patent right ...
>
> address ...
>
> Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. ISO [and/or] IEC shall not be held responsible for identifying any or all such patent rights."
>
> ISO (www.iso.org/patents) and IEC (http://patents.iec.ch/) maintain on-line data bases of patents relevant to their standards. Users are encouraged to consult the data bases for the most up to date information concerning patents.

[7] This latter phrase ("concerning (....subject matter) given in (...subclause)") can be deleted when the information is not provided.

APPENDIX I

COMMON PATENT POLICY FOR ITU-T/ITU-R/ISO/IEC

The following is a "code of practice" regarding patents covering, in varying degrees, the subject matters of ITU-T Recommendations, ITU-R Recommendations, ISO deliverables and IEC deliverables (for the purpose of this document, ITU-T and ITU-R Recommendations are referred to as “Recommendations”, ISO deliverables and IEC deliverables are referred to as “Deliverables”). The rules of the "code of practice" are simple and straightforward. Recommendations | Deliverables are drawn up by technical and not patent experts; thus, they may not necessarily be very familiar with the complex international legal situation of intellectual property rights such as patents, etc.

Recommendations | Deliverables are non-binding; their objective is to ensure compatibility of technologies and systems on a worldwide basis. To meet this objective, which is in the common interests of all those participating, it must be ensured that Recommendations | Deliverables, their applications, use, etc. are accessible to everybody.

It follows, therefore, that a patent embodied fully or partly in a Recommendation | Deliverable must be accessible to everybody without undue constraints. To meet this requirement in general is the sole objective of the code of practice. The detailed arrangements arising from patents (licensing, royalties, etc.) are left to the parties concerned, as these arrangements might differ from case to case.

This code of practice may be summarized as follows:

1 The ITU Telecommunication Standardization Bureau (TSB), the ITU Radiocommunication Bureau (BR) and the offices of the CEOs of ISO and IEC are not in a position to give authoritative or comprehensive information about evidence, validity or scope of patents or similar rights, but it is desirable that the fullest available information should be disclosed. Therefore, any party participating in the work of ITU, ISO or IEC should, from the outset, draw the attention of the Director of ITU-TSB, the Director of ITU-BR, or the offices of the CEOs of ISO or IEC, respectively, to any known patent or to any known pending patent application, either their own or of other organizations, although ITU, ISO or IEC are unable to verify the validity of any such information.

2 If a Recommendation | Deliverable is developed and such information as referred to in paragraph 1 has been disclosed, three different situations may arise:

2.1 The patent holder is willing to negotiate licences free of charge with other parties on a non-discriminatory basis on reasonable terms and conditions. Such negotiations are left to the parties concerned and are performed outside ITU-T/ITU-R/ISO/IEC.

2.2 The patent holder is willing to negotiate licences with other parties on a non-discriminatory basis on reasonable terms and conditions. Such negotiations are left to the parties concerned and are performed outside ITU-T/ITU-R/ISO/IEC.

2.3 The patent holder is not willing to comply with the provisions of either paragraph 2.1 or paragraph 2.2; in such case, the Recommendation | Deliverable shall not include provisions depending on the patent.

3 Whatever case applies (2.1, 2.2 or 2.3), the patent holder has to provide a written statement to be filed at ITU-TSB, ITU-BR or the offices of the CEOs of ISO or IEC, respectively, using the appropriate "Patent Statement and Licensing Declaration" Form. This statement must not include additional provisions, conditions, or any other exclusion clauses in excess of what is provided for each case in the corresponding boxes of the form.

APPENDIX II

PATENT STATEMENT AND LICENSING DECLARATION FORM FOR ITU-T/ITU-R RECOMMENDATION | ISO/IEC DELIVERABLE

Patent Statement and Licensing Declaration
for ITU-T/ITU-R Recommendation | ISO/IEC Deliverable

This declaration does not represent an actual grant of a license

Please return to the relevant organization(s) as instructed below per document type:

Director
Telecommunication
Standardization Bureau
International
Telecommunication
Union
Place des Nations
CH-1211 Geneva 20,
Switzerland
Fax: +41 22 730 5853
Email: tsbdir@itu.int

Director
Radiocommunication Bureau
International
Telecommunication
Union
Place des Nations
CH-1211 Geneva 20,
Switzerland
Fax: +41 22 730 5785
Email: brmail@itu.int

Secretary-General
International Organization
for Standardization
1 chemin de la Voie-Creuse
CH-1211 Geneva 20
Switzerland
Fax: +41 22 733 3430
Email:
patent.statements@iso.org

General Secretary
International Electrotechnical
Commission
3 rue de Varembé
CH-1211 Geneva 20
Switzerland
Fax: +41 22 919 0300
Email:
inmail@iec.ch

Patent Holder:
Legal Name _____
Contact for license application:
Name & Department _____
Address _____
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E-mail _____
URL (optional) _____

Document type:

☐ **ITU-T Rec. (*)** ☐ **ITU-R Rec. (*)** ☐ **ISO Deliverable (*)** ☐ **IEC Deliverable (*)**
(please return the form to the relevant Organization)

☐ **Common text or twin text (ITU-T Rec. | ISO/IEC Deliverable (*))** (for common text or twin text, please return the form to each of the three Organizations: ITU-T, ISO, IEC)

☐ **ISO/IEC Deliverable (*)** (for ISO/IEC Deliverables, please return the form to both ISO and IEC)

(*)Number _____
(*)Title _____

Licensing declaration:
The Patent Holder believes that it holds granted and/or pending applications for patents, the use of which would be required to implement the above document and hereby declares, in accordance with the Common Patent Policy for ITU-T/ITU-R/ISO/IEC, that (check one box only):

☐ 1. The Patent Holder is prepared to grant a free of charge license to an unrestricted number of applicants on a worldwide, non-discriminatory basis and under other reasonable terms and conditions to make, use, and sell implementations of the above document.
Negotiations are left to the parties concerned and are performed outside the ITU-T,

ITU-R, ISO or IEC.
Also mark here __ if the Patent Holder's willingness to license is conditioned on reciprocity for the above document.

Also mark here __ if the Patent Holder reserves the right to license on reasonable terms and conditions (but not free of charge) to applicants who are only willing to license their patent claims, whose use would be required to implement the above document, on reasonable terms and conditions (but not free of charge).

☐ 2. The Patent Holder is prepared to grant a license to an unrestricted number of applicants on a worldwide, non-discriminatory basis and on reasonable terms and conditions to make, use and sell implementations of the above document. Negotiations are left to the parties concerned and are performed outside the ITU-T, ITU-R, ISO, or IEC.

Also mark here __ if the Patent Holder's willingness to license is conditioned on reciprocity for the above document.

☐ 3. The Patent Holder is unwilling to grant licenses in accordance with provisions of either 1 or 2 above.
In this case, the following information must be provided to ITU, and is strongly desired by ISO and IEC, as part of this declaration:
- granted patent number or patent application number (if pending);
- an indication of which portions of the above document are affected;
- a description of the patent claims covering the above document.

Free of charge: The words "free of charge" do not mean that the Patent Holder is waiving all of its rights with respect to the essential patent. Rather, "free of charge" refers to the issue of monetary compensation; *i.e.*, that the Patent Holder will not seek any monetary compensation as part of the licensing arrangement (whether such compensation is called a royalty, a one-time licensing fee, etc.). However, while the Patent Holder in this situation is committing to not charging any monetary amount, the Patent Holder is still entitled to require that the implementer of the above document sign a license agreement that contains other reasonable terms and conditions such as those relating to governing law, field of use, reciprocity, warranties, etc.

Reciprocity: As used herein, the word "reciprocity" means that the Patent Holder shall only be required to license any prospective licensee if such prospective licensee will commit to license its essential patent(s) or essential patent claim(s) for implementation of the same above document free of charge or under reasonable terms and conditions.

Signature:

Patent Holder _____

Name of authorized person _____

Title of authorized person _____

Signature _____

Place, Date _____

FORM: 1 March 2007

Patent Information (desired but not required for options 1 and 2; required in ITU for option 3 (NOTE))				
No.	**Status** [granted/ pending]	**Country**	**Granted Patent Number** **or** **Application Number (if pending)**	**Title**
1				
2				
3				

NOTE: For option 3, the additional minimum information that shall also be provided is listed in the option 3 box above.

APPENDIX III

GENERAL PATENT STATEMENT AND LICENSING DECLARATION FORM FOR ITU-T/ITU-R RECOMMENDATION

ITU
International Telecommunication Union

General Patent Statement and Licensing Declaration

for ITU-T/ITU-R Recommendation

This declaration does not represent an actual grant of a license

Please return to the relevant bureau:

Director
Telecommunication Standardization Bureau
International Telecommunication Union
Place des Nations
CH-1211 Geneva 20,
Switzerland
Fax: +41 22 730 5853
Email: tsbdir@itu.int

Director
Radiocommunication Bureau
International Telecommunication Union
Place des Nations
CH-1211 Geneva 20,
Switzerland
Fax: +41 22 730 5785
Email: brmail@itu.int

Patent Holder:

Legal Name _____

Contact for license application:

Name & Department _____

Address _____

_____

Tel. _____

Fax _____

E-mail _____

URL (optional) _____

Licensing declaration:

In case part(s) or all of any proposals contained in Contributions submitted by the Patent Holder above are included in ITU-T/ITU-R Recommendation(s) and the included part(s) contain items that have been patented or for which patent applications have been filed and whose use would be required to implement ITU-T/ITU-R Recommendation(s), the above Patent Holder hereby declares, in accordance with the Common Patent Policy for ITU-T/ITU-R/ISO/IEC (check one box only):

☐ 1. The Patent Holder is prepared to grant a free of charge license to an unrestricted number of applicants on a worldwide, non-discriminatory basis and under other reasonable terms and conditions to make, use, and sell implementations of the relevant ITU-T/ITU-R Recommendation.

Negotiations are left to the parties concerned and are performed outside the ITU-T/ITU-R.

Also mark here __ if the Patent Holder's willingness to license is conditioned on reciprocity for the above ITU-T/ITU-R Recommendation.

Also mark here __ if the Patent Holder reserves the right to license on reasonable terms and conditions (but not free of charge) to applicants who are only willing to license their patent claims, whose use would be required to implement the above ITU-T/ITU-R Recommendation, on reasonable terms and conditions (but not free of charge).

☐ 2. The Patent Holder is prepared to grant a license to an unrestricted number of applicants on a worldwide, non-discriminatory basis and on reasonable terms and conditions to make, use and sell implementations of the relevant ITU-T/ITU-R Recommendation.

Negotiations are left to the parties concerned and are performed outside the ITU-T/ITU-R.

Also mark here __ if the Patent Holder's willingness to license is conditioned on reciprocity for the above ITU-T/ITU-R Recommendation.

Free of charge: The words "free of charge" do not mean that the Patent Holder is waiving all of its rights with respect to the essential patent. Rather, "free of charge" refers to the issue of monetary compensation; *i.e.*, that the Patent Holder will not seek any monetary compensation as part of the licensing arrangement (whether such compensation is called a royalty, a one-time licensing fee, etc.). However, while the Patent Holder in this situation is committing to not charging any monetary amount, the Patent Holder is still entitled to require that the implementer of the ITU-T/ITU-R Recommendation sign a license agreement that contains other reasonable terms and conditions such as those relating to governing law, field of use, reciprocity, warranties, etc.

Reciprocity: As used herein, the word "reciprocity" means that the Patent Holder shall only be required to license any prospective licensee if such prospective licensee will commit to license its essential patent(s) or essential patent claim(s) for implementation of the same ITU-T/ITU-R Recommendation free of charge or under reasonable terms and conditions.

Signature:

Patent Holder _____

Name of authorized person _____

Title of authorized person _____

Signature _____

Place, Date _____

FORM: 1 March 2007