



January 17, 2020

To: Anne Caldas, Secretary of the ExSC, via email [acaldas@ansi.org](mailto:acaldas@ansi.org) and [psa@ansi.org](mailto:psa@ansi.org)

From: Scott Stuewe, President and CEO of DirectTrust  
Natasha Kreisle, Project Lead, DirectTrust Standards and DirectTrust SDO Secretariat

Re: DirectTrust Comments responding to Proposed Revision to the *ANSI Essential Requirements: Due process Requirements for American National Standards*, ExSC\_017\_2019, Standards Action, December 6, 2019

Dear Ms. Caldas:

DirectTrust™ is a relatively new ANSI Member, accredited by ANSI on March 26, 2019 to develop American National Standards (“ANS”), and we have filed PINS for two projects underway. The ANSI ERs were reviewed in detail when we sought accreditation, and now we are tracking proposed revisions to that document, as well as other changes like revisions to ANSI Operating Procedures, etc. We have also started to attend ANSI events such as World Standards Week, etc. Our industry sector is Health Care and we believe we are “the most trusted name in health information exchange.”

DirectTrust is a collaborative non-profit association of more than 100 health IT and healthcare organizations to support secure, interoperable health information exchange via the Direct Secure Message protocols. DirectTrust has created a “trust framework” that extends use of Direct exchange to over 200,000 healthcare organizations and 2 million Direct addresses/accounts. This trust framework supports both provider-to-provider Direct exchange and bi-directional exchange between consumers/patients and their providers.

DirectTrust’s trust framework makes it easy for healthcare professionals, health IT vendors and their patients/customers to communicate securely, with identity proofing and regardless of end-user application. In fact, the ease of use has contributed to more than one billion Direct messages sent and received since 2014. Over 300 EHR and PHR vendors’ products, and over 50 HIEs, participate in the DirectTrust network, ensuring interoperability and security via Direct for exchange of health information to more than half the professionals in the U.S. health care system.

#### Introduction to our Standards function.

A major function of DirectTrust Standards is the writing and maintenance of voluntary industry standards and specifications, and the preparation of technical information and reports for use by industry and government. These activities are carried out by the volunteers of the Standards Board, Consensus Bodies and their sub-elements.

**DirectTrust Mission Statement:** The Mission of DirectTrust is to support health information exchange that is secure, interoperable, affordable, ubiquitous and



useable by diverse end-users. This Mission is pursued in the interest of the public good, as a non-profit, competitively neutral, membership 'learning organization' for voluntary self-governance of health information exchange.

DirectTrust Standards Mission Statement: The Mission of DirectTrust Standards is to develop and maintain standards that enable and promote healthcare interoperability using Direct exchange and/ or trust frameworks.

#### Proposed Revisions to the ANSI Essential Requirements ("ANSI ER")

The Notice for Comments *in Standards Action* advised:

The proposed revision reflects modified text as shown in sections 1.5 Notification of standards development, 2.1 Openness, 2.3 Balance, 2.5 Notification of standards development and coordination and 2.8 Appeals. The proposed revision is intended to clarify existing requirements and process implementation expectations and, in some cases, establish new procedural requirements.

We have carefully reviewed the changes to each of those Sections and offer these Comments.

#### Specific Comments:

##### Section 2.1 Openness

This does not appear to be a substantive change but more editorial since text once in a footnote has just been relocated to the main body of the section, possibly as a matter of emphasis.

→ DirectTrust supports this change.

##### Section 2.3 Balance

The ANSI ERs first state the historical definition for balance:

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

The first proposed text is:

Consensus body members, including consultants<sup>2</sup>, shall normally be classified in accordance with the business or other interests of their employers or the sponsor they represent in connection with the standards development activity. In cases where a consensus body member receives funding from the sponsoring ASD or other entity, that



information shall be disclosed, to determine if it will impact the participant's interest classification.

➔ DirectTrust supports the inclusion of this added text.

Section 2.3 additionally states (emphasis added):

In defining the interest categories appropriate to a standards activity, consideration **shall** be given to at least the following:

- a) producer;
- b) user;
- c) general interest.

Given the mandatory nature of SHALL statements, DirectTrust presumes most ANSI Accredited Standards Developers (“ASDs”) have an interest category for “General Interest.” DirectTrust interest categories appropriate for our industry and type of work are:

- a) Healthcare Sector
- b) Government Sector
- c) Healthcare Payer Sector
- d) Consumer Sector and General Interest
- e) Information Technology Sector
- f) Interoperability and Systems Integration Sector

DirectTrust Standards Operating Procedures provide more details on what type of entities fit into each Category. For example:

- a) Healthcare Sector includes:
  - Integrated Delivery Networks
  - Accountable Care Organizations
  - Acute Care Organizations
  - Ambulatory Care Organizations
  - Post-Acute Care Organizations
  - Other organizations providing care to patients
- d) Consumer Sector and General Interest includes:
  - Consumer Focused Companies
  - Consumer advocates
  - Students

and

- f) Interoperability and Systems Integration Sector includes:
  - Health Information Organizations
  - Health Information Service Providers HISPS (as a primary business)
  - Exchange and Systems Integration Technology vendors
  - Identity and Registration



The ANSI Notice then provides additional new text (emphasis added):

A "General Interest" category, **if one is offered, should include** only those whose business or other interests are not covered by a discretely defined interest category, or those who represent multiple interest categories.

A part of this new proposed language is the contrast between having a SHALL statement and the part of the new text that has a SHOULD statement conditioned on “if one is offered” which seems counter to having the SHALL statement.

- ➔ DirectTrust suggests the below alternative language to remove the tension between the “shall” and “if one is offered” and allow each ASD to define the category more broadly if needed:

A "General Interest" category should include those whose business or other interests are not covered by a discretely defined interest category, or those who represent multiple interest categories.

- ➔ DirectTrust supports the definition for “consultant” and notes it is very similar to the definition that has been used at ANSI in the phased out IPRPC Operating Procedures as well as in Section 9 of the new IPRPAG Procedures.

Footnote 3 provides suggested additional types of Interest Categories that may be used. DirectTrust questions why the ExSC proposed deleting two of the suggestions, “Trade Association” and “Professional Society” without a reason or rationale as to why they are being removed. DirectTrust is aware of many Trade Associations which, like DirectTrust itself, are ASDs. Similarly, a Professional Society like the American Dental Association is also an ASD. DirectTrust feels that removal of these categories could be detrimental to harmonization efforts and participation in other ASD’s technical work due to the implications that ASDs must remove those Interest Categories.

Although the language in Footnote 3 says “may be used” coupled with the open-ended language “but not limited to” which seems to indicate “Trade Association” and “Professional Society” or other Interest Categories may still be used if appropriate for an ASD, DirectTrust would not want to see these deletions making it harder for a new ASD to become accredited by the ExSC if the ASD found those to be appropriate and needed categories for its technical work.

- ➔ DirectTrust sees no reason for deletion of “Trade Associations” or “Professional Society” and thus supports leaving them in the ANSI ERs.



The editorial comment is both the current ANSI ER and the proposed changes have the alpha letter for Regulatory Agency with a capital “I” whereas all the other categories are lower case.

- ➔ For consistency, all alpha letters should be lower case. Also, if the ExSC removes Professional Society, then Regulatory Agency becomes lower case “h).”

In regard to balance, due process and openness, keeping abreast of actions by the Department of Justice (“DoJ”) and other agencies has been a priority for DirectTrust. As an ANSI member, DirectTrust reviewed an excellent contribution to the last ANSI IPRPC meeting, IPRPC 517. DirectTrust takes Antitrust compliance very seriously and has an Antitrust Policy. The following statement is on the DirectTrust website and read by staff at the beginning of all meetings and recorded in the meeting report:

Please note: It is the policy of DirectTrust.org, Inc. to conduct its operations in strict compliance with the antitrust laws of the United States and the DirectTrust Antitrust Compliance Policy and Guidelines posted on our web site. Violations are grounds for discipline by or dismissal from DirectTrust as an officer, director, employee or member.

Because DirectTrust has a strong Antitrust Compliance Policy and Guidelines, we found the IPRPC Contribution 517 comprehensive and very helpful for SDOs and ASDs. The DoJ has been active in SDO investigations, sending advice letters to ANSI, and filing Statements of Interest in court cases involving SDOs. For example, as shown in IPRPC Contribution 517, in *NSS Labs vs. Crowdstrike*, there was an “allegation that an SDO developed a standard which unreasonably restrained competition in violation of the Sherman Act; allegations included an **imbalance in the membership** that developed the standard.” (Emphasis added.)

- ➔ DirectTrust advocates that when ANSI is revising the “Balance” section of the ANSI ER, to factor those regulatory agency perspectives into the ANSI definition of Balance, etc. And those definitions should be included in the ER ANNEX A with definitions.

### Section 1.5 Notification of standards development

The next section in ExSC\_017\_2019 is Section 1.5.1 DirectTrust noticed the different language choices used in the ANSI ER and questions what the variations in language should convey to an ASD attempting to become accredited or maintain its accredited status. For example, existing and proposed variations are shown in the table below.

Section	Wording
Section 2.1 (unmodified)	Timely and adequate notice of any action...

<sup>1</sup> Although the Section numbering in ExSC\_017\_2019 is out of sequence with Section 1.5 following and not preceding Sections 2.1 and 2.3, we assume this was intentional in order to place Section 1.5 adjacent to 2.5 for comparison purposes. The sections in the 1.X portion of the ANSE ER set forth the principle of the covered topic and the companion 2.X portion of the ANSI ER provides more details on the topic. DirectTrust believes the same wording and word choices should be used in companion sections.



Section 1.5 (emphasis added on proposed wording)	<b>Reasonable advance notification</b> of standards ... activity shall be announced ...
Section 2.5 (emphasis added on proposed wording)	<b>Reasonable timely notification</b> of standards activity ...

The variations and modifying adjectives on the noun(s) “notification (or notice)” may cause confusion to an ASD which wants to maintain its accredited procedures and actual process in compliance with the ANSI ERs. It appears that the variations convey a similar if not identical principle but may cause significant confusion for ASDs in the choice of language.

- ➔ DirectTrust submits that the notice or notification should be “timely and adequate” and that language should be used in all three sections as well as other sections in the ANSI ER where such similar qualifiers are coupled to a notice requirement.

Further, adding the word “development” before the word “activity” seems to be an attempt to separate the “development type” technical activities of an SDO from other standards activity of the SDO such as revisions of an SDO IPR Policy. The current language in Section 1.5 covers “Notification of standards activity.” Both the current language in Section 2.5 as well as the proposed language in Section 2.5 covers “Notification of standards activity.”

Contribution IPRPC 517 on page 5 correctly informs us that Congress has defined in law what the terms “standards development activity” encompass:

Under the SDOAA: The term ‘standards development activity’ means any action taken by a standards development organization for the purpose of developing, promulgating, revising, amending reissuing, interpreting, or otherwise maintaining a voluntary consensus standard, or using such standard in conformity assessment activities, **including actions relating to the intellectual property policies of the standards development organization.** (Red font in the original.)

Thus, the proposed addition of the word “development” would make this section disagree with other sections of the ANSI ER, would not narrow the covered activities to only technical work given the definition by SDOAA which ANSI and its members supported, and has been emphasized recently by the DoJ in a Statement of Interest filed in SDO litigation. DirectTrust believes all standard activities should be covered as stated in the SDOAA.<sup>2</sup>

- ➔ DirectTrust does not support the proposed addition of the word “development” before the word “activity” in Section 1.5.

<sup>2</sup> As a new ASD, DirectTrust has filed with DoJ and FTC for the protections afforded to SDOs under the SDOAA.



## Section 2.5 Notification of standards development and coordination

DirectTrust has already noted some of the confusion in the existing ANSI ERs<sup>3</sup> as well as the added confusion created by added language being proposed in ExSC\_017\_2019. Section 2.5 is yet another example. The title of this section talks about “standards development” in addition to coordination. Yet within the body of the text in that section it does NOT include the word “development” but just talks about “standards activity,” which most would argue is a broader term than standards development activity, in both the existing ANSI ER (2020) and the proposed language in ExSC\_017\_2019. But even if the word “development” was consistently used throughout the ANSI ER to try to limit the scope of activities covered, we then have statutory language enforced by antitrust regulatory agencies like the DOJ and FTC in the SDOAA which advises ANSI and ASDs that: “The term ‘standards development activity’ means any action taken by a standards development organization for the purpose of developing, promulgating, revising, amending reissuing, interpreting, or otherwise maintaining a voluntary consensus standard, or using such standard in conformity assessment activities, **including actions relating to the intellectual property policies of the standards development organization**” *supra*. Thus, it appears to DirectTrust that having the word “development” added does not narrow the scope from just saying “standards activity” consistently throughout all of the ANSI ER.

### Section 2.5.1 Project Initiation Notification (PINS)

DirectTrust has no issue with the proposed text being added to this section. Notice to parties and PINS deliberations have been ANSI principles for a long time now and can also identify areas where redundant standards development may already exist and thus prevent conflicting ANSs. However, DirectTrust also notes, as does ANSI, there also can be a compelling industry need for two standards in the same sector.<sup>4</sup>

- ➔ DirectTrust advocates a change in the title of this section to be consistent with the acronym “PINS” and include the word “System” to the title so it would read: Section 2.5.1 Project Initiation Notification System (PINS).

### Section 2.8.1 Right to Appeal: Appeals at the standard developer level

DirectTrust supports decisions being issued “expeditiously and issued in writing.” A decision which is in writing and only says “Appeal dismissed” is not informative or useful if further appeals to ANSI are needed. DirectTrust believes its Appeals Procedures would satisfy what ExSC is proposing for this section.

<sup>3</sup> See footnote 2 *supra*.

<sup>4</sup> This is covered in Section 2.5.1.2, Assertions of conflict or duplication, where it states in the last sentence: “The purpose of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project.” And also in Section 4.2.1.1, Criteria for approval of an American National Standard, where it states the BSR will evaluate whether: “e) other known national standards were examined with regard to harmonization and duplication of content and if duplication exists, there is a compelling need for the standard” and at the end of that section: “The BSR shall not approve standards that duplicate existing American National Standards unless there is a compelling need.”



- ➔ DirectTrust would strengthen this addition by having it read: “expeditiously and issued in writing (including electronic communications) and the decision should provide a rationale or reason for each of its findings.”

### Section 2.8.2 Right to Appeal: Appeal at ANSI

Although a lot of new text is being proposed to be added to this section by the ExSC, DirectTrust has been advised that there have been several cases where Appeals at the ASD level took an extremely long time or were not even completed before submission of a BSR-9 and thus approval of the ANS had to be stopped. Appeals should be concluded before the BSR will consider approval of an ANS.

- ➔ DirectTrust recommends stronger language in the ANSI ER that would emphasize that Appeals must be handled quickly and fairly, and written decisions issued.

DirectTrust’s accredited procedures already state:

#### 1.8 Appeals

Procedures in this document provide for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include whether a technical issue was afforded due process.

Appeals shall be made to DirectTrust as follows. Appeals to ANSI, if desired, may be submitted upon completion of the DirectTrust appeals process.

#### 1.8.1 Appeals to DirectTrust

##### 1.8.1.1 Procedural Complaint to DirectTrust

At any point in the ANS development process when a directly or materially affected person believes a technical issue was not afforded due process, the person with the complaint should feel free to bring the matter to the attention of the Standards Board within 30 days. The Standards Board shall take prompt action to investigate the complaint with all parties concerned and render a fair, unbiased decision expeditiously to address the concerns. If after investigating the matter the complaint is sustained, appropriate action will be taken to correct the problem.

If the matter requires a clarification or interpretation of this document, an Advisory Note may be issued after approval by the Standards Board.

If the complaint involves actions that the Standards Board took or failed to take, then such a complaint can be directed to the Standards Board Chair or the DirectTrust President for investigation and appropriate action.





### 1.8.1.2 Appealing the Development, Revision, Reaffirmation or Withdrawal of an ANS to DirectTrust

Persons who have directly and materially affected interests and who feel that they have been or will be adversely affected by the revision, reaffirmation or withdrawal of an existing ANS, or by the development of a proposed ANS, within the jurisdiction of DirectTrust do have the right to formally appeal procedural actions or inactions of the Standards Board and its Workgroups. Appeals shall be submitted with a \$1,000.00 processing fee. A fee reduction or waiver may be requested.

### 1.8.1.3 Complaints

The Appellant shall file a written complaint with the Standards Board within 30 days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objection(s) including any adverse effects, the section(s) of these procedures or the standard(s) that are at issue, actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the Appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall also be noted. A copy of the complaint shall be served on the Respondent by the Appellant concurrent with the filing at DirectTrust.

### 1.8.1.4 Response

Within 30 days after receipt of the complaint, the Respondent (Standards Board, Standards Workgroup Chair or DirectTrust representative) shall respond in writing to the Appellant, specifically addressing each allegation of fact in the complaint to the extent of the Respondent's knowledge. DirectTrust shall attempt to resolve the complaint informally. A copy of the response shall be filed with the Standards Board.

No further filings beyond the Complaint and Response are allowed unless an Appeals Panel authorizes additional filings.

### 1.8.1.5 Appeals Panel and Hearing

If the Appellant and the Respondent are unable to resolve the written complaint informally in a manner consistent with these procedures, the Standards Board shall schedule a hearing with an Appeals Panel if requested to do so by the Appellant, and provided the Appellant has paid a reasonable Appeals Fee of \$1,000, to DirectTrust. If the Appellant can demonstrate economic hardship for the payment of the Appeals Fee, DirectTrust will give fair consideration to granting either an Appeals Fee reduction or waiver. Each side shall bear its own attorney's fees incident to the Appeal.

At the request of the appellant the Secretariat shall appoint an appeals panel to hold a hearing on a date agreeable to all attendees, with at least 15 working days' notice, but no more than 30 working days' notice. Appeals hearings may be held by conference call. The appeals panel shall consist of three individuals who have not been directly involved in the dispute and who will not be materially affected by any decision made in



the dispute. If DirectTrust and the appellant cannot agree on the appeal panelists within 15 working days, DirectTrust may appoint the appeal panel.

#### 1.8.1.6 Conduct of Hearing

The Appellant has the burden of demonstrating improper actions or inactions complained of, adverse effects of such improper actions or inactions, and the efficacy of the requested remedial action. If the Appellant has met its burden, the Respondent has the burden of demonstrating that the Standards Workgroup, Chair, and the Standards Board took all actions in compliance with the version of these procedures in effect during the time period in question and that the requested remedial action would be ineffective, detrimental or is otherwise unwarranted. The Appellant has the burden of demonstrating improper actions or inactions complained of, adverse effects of such improper actions or inactions, and the efficacy of the requested remedial action.

If the Appellant has met its burden, the Respondent has the burden of demonstrating that the Workgroup, Chair, and the Standards Board took all actions in compliance with the version of these procedures in effect during the time period in question and that the requested remedial action would be ineffective, detrimental or is otherwise unwarranted. The hearing shall be conducted in an informal manner and subject to such rules as the Appeal Panel may determine. The Appeals Panel and the parties shall not be bound by any formal rules of evidence.

Each party may have up to five (5) persons in attendance at the Hearing.

Each party shall present its views through a person of its choosing, without interruption for up to one hour, saving a part of the time for rebuttal, if desired. The Appellant shall go first. Members of the Appeals Panel shall then have up to 30 minutes of questions directed to each side, 30 minutes each side. Parties may suggest questions that they believe the Panel should ask the other side, but all questions must come from the Panel and there shall be no cross-examination or direct questioning or interruption of one side by the other. After a recess of one hour, the Respondent shall deliver a Closing Statement for not more than 15 minutes in length followed by a Closing Statement of the Appellant. The Panel may again pose questions to either side for 30 minutes total. Each side will then have 5 minutes for a Summation, starting with the Appellant. The Chair of the Panel shall enforce the time limits.

Representatives of other interested parties shall be allowed to observe the Hearing and will not be allowed to directly participate, except with the permission of the Appeals Panel.

Any documents requested by the Appeals Panel during the Hearing shall be provided to the Chair of the Panel within 10 days of the Hearing.



Closing briefs shall be filed only if specifically requested by the Appeals Panel and in the time frame requested.

#### 1.8.1.7 Decision

Appeals panel decisions will be made on a simple-majority vote of the panel. The appeals panel shall render its decision in writing within 30 days of the hearing, stating its findings of fact and conclusions, with reasons therefor, and citing the evidence. The Secretariat shall send to the complainant a written decision and inform the Standards Workgroup of the decision of the appeals panel, which shall be binding and final on all concerned.

#### 1.8.2 Right to Further Appeal to ANSI

If the matter under appeal relates to a DirectTrust standard or specification that has been recognized as an ANS, further appeal may be made directly to ANSI in accordance with its procedures.

DirectTrust believes its accredited Appeal procedures already would be in compliance with the language that is being proposed to be added to this section of the ANSI ER.

In closing, thank you kindly for your time and attention to the aforementioned comments.

Regards,

A handwritten signature in black ink, appearing to be "S. Stuewe".

Scott Stuewe  
President and CEO, DirectTrust

and

A handwritten signature in black ink, appearing to be "N. Kreisle".

Natasha Kreisle  
Project Lead, DirectTrust Standards