IEEE STANDARDS ASSOCIATION

IEEE

P1752 Working Group Meeting

Sponsored by IEEE Engineering in Medicine & Biology (EMB) Standards Committee

Attendance Taken by Secretary

- 6 August 2024
- Teleconference

Attendance

- Attendance is important for determining voting rights, so please remember to “check in” Write full name and affiliation on your zoom name. If you attend only by phone, please email the info to simona@openmhealth.org
- Secretary will mark attendance for everyone
- If you attended a previous call and your attendance was not noted on the draft minutes distributed by the Secretary, please email simona@openmhealth.org

Voting membership

- Attendance is important for determining voting membership
- After you've attended 2 consecutive meetings you are eligible for voting membership
- If you wish to become a voting member, send an email with the request to simona@openmhealth.org
- You don't need to be a voting member to participate in the WG or subgroup calls
- You need to be a voting member to move or second motions and to vote whenever the WG entertains a motion (e.g., to approve the agenda, to approve an action by the WG, etc.)
- If you miss 2 consecutive meetings, voting membership is revoked and can be gained again by attending 2 consecutive meeting and sending a request
- Accommodation can be made for special circumstances, which should be brought to the Chair's attention

IEEE Policies

IEEE SA Call for Patents

Participants have a duty to inform the IEEE

- Participants shall inform the IEEE (or cause the IEEE to be informed) of the identity of each holder of any potential Essential Patent Claims of which they are personally aware if the claims are owned or controlled by the participant or the entity the participant is from, employed by, or otherwise represents

- Participants should inform the IEEE (or cause the IEEE to be informed) of the identity of any other holders of potential Essential Patent Claims

Early identification of holders of potential Essential Patent Claims is encouraged

Slide #1

Ways to inform IEEE

- **Cause an LOA to be submitted to the IEEE-SA (patcom@ieee.org); or**
- **Provide the chair of this group with the identity of the holder(s) of any and all such claims as soon as possible; or**
- **Speak up now and respond to this Call for Potentially Essential Patents**

If anyone in this meeting is personally aware of the holder of any patent claims that are potentially essential to implementation of the proposed standard(s) under consideration by this group and that are not already the subject of an Accepted Letter of Assurance, please respond at this time by providing relevant information to the WG Chair

Slide #2

Other guidelines for IEEE WG meetings

- **All IEEE-SA standards meetings shall be conducted in compliance with all applicable laws, including antitrust and competition laws.**
  - **Don't discuss the interpretation, validity, or essentiality of patents/patent claims.**
  - **Don't discuss specific license rates, terms, or conditions.**
    - Relative costs of different technical approaches that include relative costs of patent licensing terms may be discussed in standards development meetings.
      - **Technical considerations remain the primary focus**
  - **Don't discuss or engage in the fixing of product prices, allocation of customers, or division of sales markets.**
  - **Don't discuss the status or substance of ongoing or threatened litigation.**
  - **Don't be silent if inappropriate topics are discussed … do formally object.**

For more details, see *IEEE-SA Standards Board Operations Manual*, clause 5.3.10 and *Antitrust and Competition Policy: What You Need to Know* at http://standards.ieee.org/develop/policies/antitrust.pdf

Slide #3

Patent-related information

The patent policy and the procedures used to execute that policy are documented in the:

- ***IEEE-SA Standards Board Bylaws***
  (http://standards.ieee.org/develop/policies/bylaws/sect6-7.html#6)
- ***IEEE-SA Standards Board Operations Manual***
  (http://standards.ieee.org/develop/policies/opman/sect6.html#6.3)

Material about the patent policy is available at
http://standards.ieee.org/about/sasb/patcom/materials.html

If you have questions, contact the IEEE-SA Standards Board Patent Committee Administrator at patcom@ieee.org

IEEE SA Copyright Policy

IEEE SA Copyright Policy (November 2019)

- **By participating in this activity, you agree to comply with the IEEE Code of Ethics, all applicable laws, and all IEEE policies and procedures including, but not limited to, the IEEE SA Copyright Policy.**

    - Previously Published material (copyright assertion indicated) shall not be presented/submitted to the Working Group nor incorporated into a Working Group draft unless permission is granted.
    - Prior to presentation or submission, you shall notify the Working Group Chair of previously Published material and should assist the Chair in obtaining copyright permission acceptable to IEEE SA.
    - For material that is not previously Published, IEEE is automatically granted a license to use any material that is presented or submitted.

IEEE SA Copyright Policy

- The IEEE SA Copyright Policy is described in the IEEE SA Standards Board Bylaws and IEEE SA Standards Board Operations Manual

- IEEE SA Copyright Policy, see
  Clause 7 of the IEEE SA Standards Board Bylaws
  https://standards.ieee.org/about/policies/bylaws/sect6-7.html#7
  Clause 6.1 of the IEEE SA Standards Board Operations Manual
  https://standards.ieee.org/about/policies/opman/sect6.html

- IEEE SA Copyright Permission

- https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/other/permissionltrs.zip

- IEEE SA Copyright FAQs

- http://standards.ieee.org/faqs/copyrights.html/

- IEEE SA Best Practices for IEEE Standards Development

- http://standards.ieee.org/develop/policies/best_practices_for_ieee_standards_development_051215.pdf

- Distribution of Draft Standards (see 6.1.3 of the SASB Operations Manual)

- https://standards.ieee.org/about/policies/opman/sect6.html

IEEE SA Individual Participation

Participant behavior in IEEE-SA activities is guided by the IEEE Codes of Ethics & Conduct

- All participants in IEEE-SA activities are expected to adhere to the core principles underlying the:
  - IEEE Code of Ethics
  - IEEE Code of Conduct
  - The core principles of the IEEE Codes of Ethics & Conduct are to:
    - *Uphold the highest standards of integrity, responsible behavior, and ethical and professional conduct*
    - *Treat people fairly and with respect, to not engage in harassment, discrimination, or retaliation, and to protect people's privacy.*
    - *Avoid injuring others, their property, reputation, or employment by false or malicious action*
- The most recent versions of these Codes are available at http://www.ieee.org/about/corporate/governance

Participants in the IEEE-SA "individual process" shall act independently of others, including employers

- The IEEE-SA Standards Board Bylaws require that "participants in the IEEE standards development individual process shall act based on their qualifications and experience"
- This means participants:
  – Shall act & vote based on their personal & independent opinions derived from their expertise, knowledge, and qualifications
  – Shall not act or vote based on any obligation to or any direction from any other person or organization, including an employer or client, regardless of any external commitments, agreements, contracts, or orders
  – Shall not direct the actions or votes of other participants or retaliate against other participants for fulfilling their responsibility to act & vote based on their personal & independently developed opinions
- By participating in standards activities using the "individual process", you are deemed to accept these requirements; if you are unable to satisfy these requirements then you shall immediately cease any participation

IEEE-SA standards activities shall allow the fair & equitable consideration of all viewpoints

- The IEEE-SA Standards Board Bylaws (clause 5.2.1.3) specifies that "*the standards development process shall not be dominated by any single interest category, individual, or organization*"
  - This means no participant may exercise "*authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints" or "to hinder the progress of the standards development activity*"
- This rule applies equally to those participating in a standards development project and to that project's leadership group
- Any person who reasonably suspects that dominance is occurring in a standards development project is encouraged to bring the issue to the attention of the Standards Committee or the project's IEEE-SA Program Manager

Determination of Quorum

Approval of Agenda

1. Attendance
2. Call for Patents, Copyright Policy, Code of Ethics
3. Approval of agenda and minutes (if quorum present)
4. Updates from subgroups and schema repository
5. Other business

Approval of Prior Minutes

(June 25, 2024)

Update from Subgroups

Body temperature: review & discussion

Metabolic subgroup shared proposed body temperature-related schemas

Discussion

Body temperature schema: properties

```
    "properties": {
        "body_temperature": {
            "$ref": "#/definitions/temperature_unit_value"
        },
        "effective_time_frame": {
            "$ref": "#/definitions/time_frame"
        },
        "measurement_location": {
            "$ref": "#/definitions/body_location"
        },
        "descriptive_statistic": {
            "$ref": "#/definitions/descriptive_statistic"
        },
        "temporal_relationship_to_sleep": {
            "description": "The temporal relationship to sleep of the temperature measurement(s). The lowest body temperature
attained during rest, usually estimated by a temperature measurement immediately on waking up and before any physical activity
has been undertaken is called basal temperature.",
            "$ref": "#/definitions/temporal_relationship_to_sleep"
        }
    },
    "required": [
        "body_temperature",
        "effective_time_frame"
    ]
}
```

Body temperature: finalizing draft schemas

Summary of discussion

Next step: WG to vote to approve

Update: 1752 open-source repository (I)

Needed CLAs submitted

Repository structure update to include new draft schemas (e.g., blood-glucose-0.1.json)

main branch

- 1.1 branch
  - 1.1-metabolic
  - 1.1-cardiorespiratory

IEEE purl server

JSON Schema version

Update: 1752 open-source repository (II)

```
{
    "$schema": "http://json-schema.org/draft-07/schema#",
    "$id": "https://w3id.org/ieee/ieee-1752-schema/header.json",
    "title": "Header",
    "description": "This schema represents the header of a data point or data series.",
    "type": "object",
    "definitions": {
        "date_time": {
            "$ref": "date-time-1.0.json"
        },
        "schema_id": {
            "$ref": "schema-id-1.0.json"
        },
        "frequency_unit_value": {
            "$ref": "frequency-unit-value-1.0.json"
        }
    },
```

more recent version

IEEE purl

P1752.2 Cardiorespiratory Subgroup

Meetings of June 22, 2024

Discussion:

1) **Modeling the data : Active coding challenges**
   - ***Modeling the data*** **(subject matter and scope)**
   - ***Hierarchical objects*** **(coding) → Ex: *Time, Frequency, Rate***
   - ***Emphasis of extensibility of code***

2) **FDA → "Medical Device Development Tools" portfolio**
   - ***Apple Watch*** **atrial fibrillation (afib) history**
   - ***Prior FDA 510K Clearance process***
   - ***May 2004: Qualified as an MDDT*** **'biomarker test' → *the 1st digital health tool to qualify for the MDDT program***
   - ***Specifically provides value by evaluating AFib estimates before and after the use of cardiac ablation devices (as a non-invasive way to check estimates of AFib burden within clinical trials *).***

P1752.2 Cardiorespiratory Subgroup

Meetings of June 20, 2024

Apple AFib History Feature

- As of May 2024, the FDA has qualified Apple Watch's atrial fibrillation (AFib) history feature *for use in medical device clinical trials*.
- FDA officials will accept data collected by Apple Watch as a secondary endpoint to help assess AFib burden in studies of cardiac ablation devices.
- The FDA said Apple Watch can address challenges related to patient compliance, potential placebo effects and the technical difficulties of measuring AFib burden without an implantable device.

P1752.2 Cardiorespiratory Subgroup

Meetings of June 20, 2024

Items of Discussion (continued):

Scheduled July meetings → Failed using IEEE webex

3) **Discussion and investigation of whiteboard process for coding collaboration**

4) **Switching telemeeting platform in future**

5) **Next meeting August 22 at 8:00 AM PST probable (vs August 29)**

Review of subschema JSON code status

- ***Respiratory & gas exchange***
- ***Blood pressure & hemodynamics***
- ***Pulse & rhythm***

Generic schema modeling rate (I)

Proposal: number of events / 1 [unit of time]

e.g., heart rate → number of beats / 1 minute

respiratory rate → number of respiratory cycles / 1 minute

walking rate → number of steps / 1 minute

see “average_cadence” in physical activity schema;
also number of stroked / 1 minute

Question #1: any example where the unit of time is something other than minutes or something other than a duration?

Generic schema modeling rate (II)

If number of events → quantity

rate of BG increase → 2 mg/dL / 1 minute

model: number + unit [events or of measure] / 1 [unit of time]

Any examples that break the mold?

Question #2: any example of a rate where the number of units of time is something other than 1?

Summary of Action Items

Future Meetings

Upcoming Meetings

- P1752.2 WG call
  - Tuesday September 17 at 8 am Pacific
- Cardio-respiratory subgroup:
  - Thursday August 22 at 8 am Pacific [to be confirmed]
- Metabolic subgroup:
  - TBD

Adjournment