

Document Version History

1.0 – First public draft for comment

Introduction

The LOINC vocabulary standard, developed by the Regenstrief Institute, Inc. is a coding system for laboratory test and other clinical measures used in electronic transactions between independent computer systems. The development of LOINC was initiated and continues to be directed by the Regenstrief Institute. Regenstrief maintains the LOINC database and supporting documentation, processes submissions and edits to the content, develops and curates accessory content (descriptions, hierarchies, other attributes, etc.), develops the RELMA mapping program, and coordinates LOINC releases.

In addition, Regenstrief continues to cultivate the LOINC community worldwide. To help guide the overall LOINC development, Regenstrief organized and leads the LOINC Committee of volunteers from academia, industry, and government that serve as an advisory group in defining the overall naming conventions and policies for the development process.

Over 20+ year history, LOINC development has been supported by many organizations, including the John A Hartford Foundation, the Agency for Health Care Policy and Research (AHRQ), the Centers for Disease Control and Prevention (CDC), the Indiana Clinical and Translational Sciences Institute, the California Healthcare Foundation, the Radiological Society of North America, AHIMA Foundation, RTI International, the Regenstrief Foundation, the Regenstrief Institute, and the U.S. National Library of Medicine.

Mission

The purpose of the LOINC Committee is to serve as an advisory body to the Regenstrief Institute in its development and distribution of LOINC by establishing overall naming conventions and policies for the development process. Members of

the LOINC Committee also serve as subject matter experts in their domains of expertise.

Committee Structure

The LOINC Committee is comprised of the members of its composite committees:

- The Laboratory LOINC Committee
- The Clinical LOINC Committee
- The LOINC/RadLex Committee

Officers

Chair

The responsibilities of the *Chair* include:

1. Serve as chair of one or more composite LOINC Committees
2. Coordinate the activities of all composite LOINC Committees to fulfill the mission of the LOINC Committee

Co-chair

The responsibilities of the *Chair* include:

1. Serve as chair of one or more composite LOINC Committees
2. Assist the Chair in coordinating the activities of all composite LOINC Committees to fulfill the mission of the LOINC Committee

Secretariat

The Regenstrief Institute serves as the Secretariat for the LOINC Committee.

Officer Selection

Appointment of the *Chair* and *Co-chair* roles of the overall LOINC Committee are made by the designated authority (e.g. Director of LOINC and Health Data Standards) at the Regenstrief Institute.

The Secretariat will announce a call for nominations for the Offices to the Committee membership. Nominees shall be drawn from the current voting

members of the Committee at the time of the announcement. If appropriate candidates are not available within the voting membership, the pool of candidate nominees may be extended.

Officer Terms

The *Chair* and *Co-Chair* serve renewable two year terms that end in alternating years.

Active officers must be Members of the LOINC Committee.

Membership

Members of the LOINC Committee must be approved by the Secretariat of the LOINC Committee. The Secretariat will not unreasonably prevent new members who meet the following conditions:

1. Have a direct and material interest in LOINC (i.e. they are users of LOINC)
2. Willingness to participate actively
3. Demonstrated commitment to LOINC as indicated by prior attendance of at least 3 prior meetings, and either making substantive contributions to the discussion OR submitting more than one term request
4. Have indicated which of the composite LOINC committees they wish to join
5. Have signed the then-current LOINC Committee Letter of Agreement

Membership Categories

Individual

A person meeting the qualifications can apply for membership regardless of whether they work for or own a company with employees. Individual members cannot delegate their privileges or voting rights or name proxies.

Organization

Organizations wishing to join the LOINC Committee must meet the general qualifications for membership. The attendance prerequisite need not be fulfilled by the same individual.

Member Organizations must indicate primary and up to 2 proxy representatives for each composite LOINC committee that they wish to participate in. At its discretion, the organization may appoint different representatives for each composite LOINC committee.

In addition to the general qualifications for membership, organizations must indicate whether they have a Parent/Subsidiary with any current member organizations. Where two or more Member Organizations have Parent/Subsidiary relationships with one another, they will be allowed only one voting representative collectively for each composite Committee on which one or more of the Member Organizations is represented.

If a primary or proxy representative for a Member Organization changes employers, the Member Organization must designate new primary (and, optionally, proxy) representatives to take their place.

Each designated primary or proxy representative must sign the then-current LOINC Committee Letter of Agreement before participating on the LOINC Committee.

Standards Development Organization

Organizations that develop consensus-based health data standards can apply to join the LOINC Committee under the same terms and qualifications for membership as other Member Organizations.

In addition to the general terms for Member Organizations, the Standards Development Organization Member has the following additional responsibilities:

- Develop standards complementary to LOINC
- Support the endorsement of LOINC to promote its uptake and use
- *(Optional)* Plan and organize joint events
- *(Optional)* Undertake joint projects

International Affiliate

Government agencies, ministries of health, and other organizations with significant influence on the eHealth activities in a particular jurisdiction can apply to become an International Affiliate Member.

Organizations joining as International Affiliates can meet the prior attendance after participating in one LOINC Committee meeting.

International Affiliate Members serve the LOINC Community through several additional responsibilities, including:

- Promote LOINC adoption within their jurisdiction, in accordance with establishing licensing and other policies
- Engage other relevant organizations within the area (government agencies, provider groups, professional societies, etc)
- Recruit experts to participate in special topics workgroups, etc
- Serve as Liaison to Regenstrief and the LOINC Committee for communicating regional activities and needs
- *(Optional)* Plan and organize regional events
- *(Optional)* Provide LOINC-related education training
- *(Optional)* Curate the official LOINC subset for use within the jurisdiction
- *(Optional)* Coordinate and sponsor translation of LOINC content
- *(Optional)* Coordinate submission requests from users within the jurisdiction
- *(Optional)* Maintain portal presence on LOINC website
- *(Optional)* Develop implementation tools and resources relevant to their jurisdiction

International Affiliate Members must indicate primary and up to 2 proxy representatives for each composite LOINC committee they wish to participate in. At its discretion, the International Affiliate Member may appoint different individuals to represent its organization at each composite LOINC committee.

Typically, there would be one International Affiliate Member for a given jurisdiction. Exceptions to this would be decided by Regenstrief.

If a primary or proxy representative for an International Affiliate organization changes employers, the International Affiliate must designate new primary (and, optionally, proxy) representatives to take their place.

Each designated primary or proxy representative must sign the then-current LOINC Committee Letter of Agreement before participating on the LOINC Committee.

Ex officio

Members of the Regenstrief LOINC Content Development team are members of the LOINC Committee *ex officio* without voting privileges.

The Director of LOINC and Health Data Standards at Regenstrief is also a member of the LOINC Committee *ex officio* with voting privileges.

Emeritus status

At its discretion, Regenstrief can bestow emeritus status to individuals on the LOINC Committee. This distinction is intended to allow LOINC to benefit from the advice, wisdom, and experience of the recognized individual. Such an individual could be identified as “{leadership position} Emeritus” or “Member Emeritus”. Emeritus members are encouraged to continue their participation and leadership, albeit as a non-voting member, unless designated otherwise.

Participation by non-voting members emeritus shall not count towards quorum. Positions emeritus shall be held in perpetuity.

The Laboratory LOINC Committee

The Laboratory LOINC Committee focuses on fulfilling the mission of the LOINC Committee by focusing on LOINC content representing observations, measures, documents (and collections thereof) made on specimens.

Chair

The responsibilities of the *Chair* of the Laboratory LOINC Committee include:

LOINC Committee – Principles of Governance

1. Organizing the Committee
2. Assist in facilitating logistics for Committee meetings (supported by the Secretariat)
3. Conducting Committee meetings
4. Preparing and announcing agendas
5. Supporting the Secretariat in documenting and disseminating meeting minutes
6. Being a consistent active participant in Committee discussions

Co-Chair

The responsibilities of the *Co-Chair* of the Laboratory LOINC Committee include:

1. Assisting the *Chair* in organizing the Committee
2. Conducting Committee meetings in the event that the *Chair* is unable
3. Assisting the *Chair* in preparing and announcing agendas
4. Supporting the Secretariat in documenting and disseminating meeting minutes
5. Being a consistent active participant in Committee discussions

Officer Selection

Appointment of the *Chair* and *Co-chair* roles of the Laboratory LOINC Committee are made by the designated authority (e.g. Director of LOINC and Health Data Standards) at the Regenstrief Institute.

The Secretariat will announce a call for nominations for the Officers to the Committee membership. Nominees shall be drawn from the current voting members of the Laboratory LOINC Committee at the time of the announcement. If appropriate candidates are not available within the voting membership, the pool of candidate nominees may be extended.

Officer Terms

The Chair and Co-Chair serve renewable two year terms that end in alternating years.

Active officers must be Members of the LOINC Committee.

The Clinical LOINC Committee

The Clinical LOINC Committee focuses on fulfilling the mission of the LOINC Committee by focusing on LOINC content representing observations, measures, documents (and collections thereof) made on patients, populations, devices, and other units of analysis.

Chair

The responsibilities of the *Chair* of the Clinical LOINC Committee include:

1. Organizing the Committee
2. Assist in facilitating logistics for Committee meetings (supported by the Secretariat)
3. Conducting Committee meetings
4. Preparing and announcing agendas
5. Supporting the Secretariat in documenting and disseminating meeting minutes
6. Being a consistent active participant in Committee discussions

Co-Chair

The responsibilities of the *Co-Chair* of the Clinical LOINC Committee include:

1. Assisting the *Chair* in organizing the Committee
2. Conducting Committee meetings in the event that the *Chair* is unable
3. Assisting the *Chair* in preparing and announcing agendas
4. Supporting the Secretariat in documenting and disseminating meeting minutes
5. Being a consistent active participant in Committee discussions

Officer Selection

Appointment of the *Chair* and *Co-chair* roles of the Clinical LOINC Committee are made by the designated authority (e.g. Director of LOINC and Health Data Standards) at the Regenstrief Institute.

The Secretariat will announce a call for nominations for the Officers to the Committee membership. Nominees shall be drawn from the current voting members of the Clinical LOINC Committee at the time of the announcement. If appropriate candidates are not available within the voting membership, the pool of candidate nominees may be extended.

Officer Terms

The Chair and Co-Chair serve renewable two year terms that end in alternating years.

Active officers must be Members of the LOINC Committee. Should a seated officer experience a change in membership status due to either the loss of individual membership or loss of membership by their organization; that individual will be removed as an officer. The Secretariat holds the responsibility for filling the vacant officer role.

The LOINC/RadLex Committee

The LOINC/RadLex Committee oversees the development, use, and modification of The LOINC/RSNA Radiology Playbook.

Co-Chairs

The responsibilities of the Co-Chairs of the LOINC/RadLex Committee include:

1. Organizing the Committee
2. Assist in facilitating logistics for Committee meetings (supported by the Secretariat)
3. Conducting Committee meetings
4. Preparing and announcing agendas
5. Supporting the Secretariat in documenting and disseminating meeting minutes
6. Being a consistent active participant in Committee discussions

Secretariat

The Regenstrief Institute and the Radiological Society of North America (RSNA) jointly serve as the Secretariat for the LOINC/RadLex Committee.

Officer Selection

The LOINC/RadLex Committee will be co-chaired by a Regenstrief appointee and an RSNA appointee.

Active officers must be Members of the LOINC Committee. Should a seated officer experience a change in membership status due to either the loss of individual membership or loss of membership by their organization; that individual will be removed as an officer. The Secretariat holds the responsibility for filling the vacant officer role.

Membership

Members of the LOINC/RadLex Committee will be drawn from stakeholder organizations. Members of the LOINC/RadLex Committee must meet the general qualifications for membership, and will hold membership in the overall LOINC Committee.

Each co-chair will appoint up to three (3) additional committee members. Additionally, the co-chairs, by mutual agreement, will select up to three (3) at-large members representing other stakeholder organizations. The total number of committee members will thus not exceed eleven (11).

Meetings

The LOINC/RadLex Committee will meet at least once a year. The LOINC/RadLex Committee may hold additional meetings and teleconferences with the agreement of at least one co-chair. The LOINC/RadLex Committee meetings will be open to all interested participants.

Decision-making

The decisions of the Committee will be made by consensus whenever possible. The following decisions will be made by a majority vote of the voting members at a meeting of the Committee at which a quorum is present:

1. Whether to include or exclude terms from the LOINC/RSNA Radiology Playbook
2. The content and format of the LOINC/RSNA Radiology Playbook term metadata
3. Changes to the information model for the LOINC/RSNA Radiology Playbook

A quorum which consists of a majority of Committee members with active voting rights will be required for the Committee to take action.

Nursing Subcommittee

The Nursing Subcommittee is a subcommittee of the Clinical LOINC Committee.

Purpose

The purpose of the Nursing LOINC Subcommittee is to provide LOINC codes for observations at key stages of the nursing process, including assessments, goals, and outcomes, and to meet the needs for administrative and regulatory data related to nursing care.

Chair

The responsibilities of the Chair of the Nursing Subcommittee include:

1. Organizing the Subcommittee
2. Assist in facilitating logistics for Subcommittee meetings (supported by the Secretariat)
3. Conducting Subcommittee meetings
4. Preparing and announcing agendas
5. Supporting the Secretariat in documenting and disseminating meeting minutes
6. Being a consistent active participant in Subcommittee discussions

7. Providing reports to the Clinical LOINC Committee (and Regenstrief as necessary) on their activity

Officer Selection

Appointment of the Chair role of the Nursing LOINC Subcommittee are made by the designated authority (e.g. Director of LOINC and Health Data Standards) at the Regenstrief Institute.

The Secretariat will announce a call for nominations for the Office to the Clinical LOINC Committee membership. Nominees shall be drawn from the current voting members of the Clinical LOINC Committee at the time of the announcement. If appropriate candidates are not available within the voting membership, the pool of candidate nominees may be extended.

Officer Terms

The *Chair* serves a renewable two year term.

Active officers must be Members of the LOINC Committee.

Membership Duration

The term length for Members is two years, which automatically renews as long as the conditions for Membership continue to be met. The LOINC Committee benefits from the wisdom and experience of long-term participants, and thus we want to encourage sustained contributions.

Attendance and Voting Privileges

Attendance at committee meetings is an obligation of membership. A Committee Member that misses 3 consecutive meetings is considered lapsed. A Member can reinstate themselves by attending 2 consecutive meetings, with their voting privileges enabled at the 2nd meeting.

Termination of Membership

Members may terminate their membership in the LOINC Committee at any time by notifying the Secretariat of their intent to do so.

Members failing to attend meetings in their designated Committees for 2 years will automatically be removed from the membership roster. Such Members can apply to be reinstated when they meet the general conditions for membership again.

The Regenstrief Institute may terminate the Membership of any Member upon judgment that it has acted in violation of the mission of the LOINC Committee or the LOINC License.

Updating Membership Information

Members have an ongoing responsibility to make sure that their membership information on file with the Secretariat is accurate.

Members are welcome to join additional composite LOINC committees at any time, and can do so by contacting the Secretariat.

Committee Conduct

Meeting Notice

Meetings shall be announced by email notice to membership and posting on the LOINC website. Meetings allowing in-person attendance shall be announced not less than 60 days prior to the meeting. Teleconference-only meetings shall be announced not less than 7 days prior to the meeting.

Meeting Conduct

All meetings shall be conducted in an open manner that affords all Members an adequate opportunity to present their views. The Co-chairs shall undertake this responsibility with the assistance of the Secretariat.

The Secretariat shall ensure that minutes of all meetings are clear, complete, and accurate with regard to the actions that were taken and the justification for those actions.

Decision-making

Whenever possible, the Committee will make its decisions by consensus. Actions that require Committee approval include:

- Formation of a new Committee/Subcommittee
- Significant changes to the overall naming conventions
- Significant changes to policies for the development process
- Recommendations for new work projects or development activities to be considered for RI's work plan

When a matter is put to a recorded vote, approval is determined by no less than two thirds affirmative vote of those voting. Before matters are voted upon, all opinions shall be considered.

Establishing a new composite Committee or Subcommittee

Upon recommendation from the LOINC Committee, Regenstrief Institute may form additional composite Committees or Subcommittees.

Special Task Forces or Workgroups

Regenstrief Institute may establish special task forces or workgroups as needed to inform and advance the work of the LOINC Committee. Such special groups may include both Members and non-Members as is necessary to carry out their charge.

LOINC Committee Letter of Agreement

The Regenstrief Institute, Inc. (the "Regenstrief Institute") would like you to participate on the Logical Observation Identifiers Names and Codes (LOINC®) Committee. In your role on the LOINC Committee, you will provide input to the Regenstrief Institute regarding the LOINC® standard, which has been developed in order to facilitate the exchange and pooling of clinical results for clinical care, outcomes management, and research by providing a set of universal codes and names (the "LOINC® codes") to identify laboratory and other clinical observations. This Letter of Agreement will apply whether or not it is signed by the participant.

You remain free to use any contribution you make to the LOINC database for your own purposes outside of the LOINC database, and to permit others to do the same. However, in the event any of your contributions is adopted as part of the LOINC database, you acknowledge and agree that (a) you do not acquire any right, title, and interest in or to the LOINC database or the LOINC codes (including any copyright) as a result, (b) you will not seek to prevent the Regenstrief Institute or any other party from making use of your contribution, and (c) your use of the LOINC database will be subject to the then-current LOINC Copyright Notice and License. You acknowledge and agree that to ensure the integrity of the LOINC database and the LOINC codes, it is necessary that the Regenstrief Institute owns and has right to protect the LOINC database and the LOINC codes.

You also acknowledge and agree that the Regenstrief Institute will have the sole and exclusive right: (a) to license the use of the LOINC database and LOINC codes by others on terms established by the Regenstrief Institute; and (b) to enforce any copyright in the LOINC database and the LOINC codes against others. Such enforcement shall include, where necessary, instituting appropriate legal action. You agree to promptly notify the Regenstrief Institute of any unauthorized uses or modifications of the LOINC database or LOINC codes of which you become aware.

Finally, you acknowledge and agree that, upon request by the Regenstrief Institute, you will execute such further documents or other instruments necessary in the reasonable opinion of the Regenstrief Institute to confirm the terms of this Letter of Agreement.

This Letter of Agreement may not be modified except in writing signed by both you and the Regenstrief Institute, and constitutes the entire agreement of you and the Regenstrief Institute with respect to the subject matter hereof, and supersedes any prior or contemporaneous agreement, whether oral or written. This Letter of Agreement shall be governed in all respects by the law of the State of Indiana, excluding any choice of law principles thereof.

I, _____, have read the foregoing Letter of Agreement, and agree to be bound by its terms.

Signature

Date