CDA Quality Assurance Plan
Health Level Seven International (HL7®), created in 1987, is an international Standards Development Organization (SDO) that has improved workflow and data exchange throughout the healthcare industry by developing and maintaining technical standards and corresponding implementation guides.

HL7’s Governance and Operations Manual (GOM) describes how HL7 and its work products are governed and developed through methodical and formally controlled processes. The stringent processes ensure that HL7 standards meet American National Standards Institute (ANSI) criteria, further establishing their maturity level and appropriateness for use in production system. Many HL7 standards have been referenced in US Regulations.

**WHY STANDARDS?**

Standards play a critical role in providing individuals and organizations with the tools to facilitate meaningful exchange of information. Subscribing to standards not only promotes organizational continuous improvement, but also enables comparable measurement against industry best practices.

**Strategic Goals**

**The HL7 International Strategic Plan**

**Core Strategic Goals for 2019**

Goal 1: Enhance the public image and achieve recognition by stakeholders as the leading standards developing organization (SDO) for worldwide health data interoperability standards.

Goal 2: Secure long-term sustainable revenue to realize the vision and improve customer experiences (internal and external)

Goal 3: Establish FHIR as a primary standard for global health data interoperability and enhance and maintain quality and accessibility to HL7 standards in current use

**The HL7 CDA Quality Plan**

**for 2020**

Goal 1: Increase awareness of the new CDA Quality Plan to expand the public image and achieve recognition by stakeholders as the leading standards developing organization (SDO) through offering mature product management policies and procedures focused on creating high quality standards

Goal 2: Develop fundable standards sustainability programs that attract long-term revenue commitments to realize the HL7 vision and improve customer experiences (internal and external)

Goal 3: Establish FHIR as a primary standard for global health data interoperability through standard integration with CDA, and offer continuous improvement efforts to enhance and maintain quality and accessibility to the HL7 CDA standard and its mappings into FHIR
Quality Culture for CDA and CDA Implementation Guides

What is the role of CDA Management Group and what is the role of Structure Documents Work Group with respect to establishing a quality plan?

- SDWG (methodology) defines the criteria for a high quality CDA IG
- CMG (management) established the policies and procedures for following that methodology, and sets the processes to monitor and control adherence

What are the behaviours we seek to inspire and promote within HL7 Workgroups in support of creating and maintaining high quality for the CDA standard and associated Implementation Guides?

- Proactive focus on quality rather than a reactive response applied after work has completed.
- Use of checklists that help CDA IG authors to build in quality at every step in the progression from developing a PSS to publishing an HL7 specification.
Community Outreach - How to Increase Awareness?

**Communication Plan**
Describe the ways in which the CDA Management Group works with HL7 Work Groups, ONC, Sequoia, Commonwell, DirectTrust, IHE, Da Vinci, etc. to ensure quality standards development and implementation?

**Outreach**
Describe what role CDA Implementation-A-Thons play in ensuring quality for CDA and CDA Implementation Guides?
Documentation & Tooling, Testing and Evaluation

- List the set of supporting documents (current and planned). Describe what each one documents and the intended audience.
- Describe the testing done and when it gets done by whom, etc.
- Describe what can be done to assure quality when specifications are applied in the field.
  - Develop and post a Checklist document that explains what should be done at each step
  - Develop process flow and form-based controls available in Confluence to make tracking and monitoring of quality less burdensome

Diagram taken from: PHR Implementation Guide Process Flow by Mike Peters

Checklist
- Additional checklist to support CDA IG creation.

Approvals
- At some point in the process marked with requires approval to move to next step.
1. PSS QA Checklist

(Links to How to create a PSS in Confluence and How to create a PSS in JIRA)

1. Project Name and ID: Is Name concise, based on objective of group, and unique?
2. Primary Sponsor/Workgroup: At least one is mandatory
3. Project Facilitator: At least one is mandatory. Should be ‘go to’ person for the project.
4. Implementers: At least two are mandatory for projects that will produce a standard. Contact information is mandatory.
5. Project Definition: Readable, high level expectations, indicate drivers for the projects. All acronyms to be spelled out.
6. Project Need: Must be completed for ANSI requirement
7. Security Risks: Refer to the Cookbook for Security Considerations if needed
8. Project Objectives / Deliverables / Target Dates: Target Dates may be updated and typically do not require re-approval unless a major change occurs. Projects that have more than one work product to deliver should list each work product’s expected delivery date.
9. Common Names / Keywords / Aliases:
10. Project Document Repository Location: Confirm that the URL works. (the URL could point to the HL7 Wiki, TSC Wiki, GForge, Project Insight, etc.)
11. Products: Additional information regarding HL7 Products is available at www.HL7.org > Standards > Introduction
12. Stakeholders / Vendors / Providers: This section must be completed for all projects. It is used to determine if a project is a ‘US Government Interest’ project. It also is an ANSI requirement and is included in the NIB form.
13. Confirm: Sufficiently resourced to successfully completed all steps toward artifact publication
2. NIB QA Checklist

(Link to NIB Instructions)

1. Confirm correct Document name
2. Confirm ballot level
3. Confirm the ballot dates (https://confluence.hl7.org/display/HL7/HL7+Calendars)
4. Review description: Does this ballot document hold enough interest for me that I want to join this ballot pool?
5. Confirm ANSI required information is completed
6. Future - zero QA errors once we have new tooling
7. Content complete for the scope
8. No broken links
9. All value sets present (some may be placeholders, or use temporary codes)
10. Samples - (may not be perfect)
11. Complete a Request to Ballot Checklist and get approval from sponsoring WG
3. **Ballot Completion Checklist**
   1. Create amalgamated spreadsheet from Ballot Desktop
   2. Create Confluence page(s) to track ballot reconciliation meetings and progress.
   3. Create ballot overview ([template available at the following link to create an overview of the comments and votes received](https://www.dropbox.com/scl/fi/5r9wpa0gpdsj61hyn1oum/HL7-ballot-recon-count-graphics-template.xlsx?dl=0&rlkey=tdqmr4gh4oo8z7rokyn3mj7tm))
   4. Join Listserve(s) for sponsoring workgroup(s)
   5. Request time on agenda(s) from co-chairs of sponsoring workgroup(s) at least one week prior to meeting for
      a. Approval of amalgamated spreadsheet
      b. Block votes
      c. Approval of final spreadsheet
   6. Request co-chairs to reach out to balloters to withdraw negative votes (balloter accepts the resolution and the applied change)
   7. Confirm if ballot has passed
   8. Request co-chairs to add the document to the final ballot package after all updates are executed.
4. Publication Request QA Checklist

1. Consider QA Checklist proposed 1A- 1F, also consider SDWG IG Quality Criteria. (See Validation Checklist Template)
2. Ballot Comments fully adjudicated and approved as completed by sponsoring WG
3. Future - zero QA errors once we have new tooling
4. Content complete for the scope
5. No broken links
6. All value sets present (all available, or fully documented as to how the value sets are obtained.)
7. Samples - (all valid)
Historical

Initial brainstorm 2018/12/19

<table>
<thead>
<tr>
<th>Quality Culture for CDA and CDA Implementation Guides</th>
<th>Where we talk about the culture and commitment around quality that we aspire to promote and how we aim to support developing that and maintaining it.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management</td>
<td>Information from the charters for these groups. The role of the CDA Management Group and the role of SDWG and the role of other WGs who create and contribute to Implementation Guides</td>
</tr>
<tr>
<td>Quality objectives - against the roadmap</td>
<td></td>
</tr>
<tr>
<td>Quality Reviews</td>
<td>List the review points and the process followed at each point.</td>
</tr>
<tr>
<td>Documentation</td>
<td>List the set of supporting documents (current and planned). Describe what each one documents and the intended audience.</td>
</tr>
<tr>
<td>Tools, Techniques, and Methodologies</td>
<td>Refer to the IG Quality Criteria. Incorporate the Templates ITS Specification information. Describe the three CDA Template tools.</td>
</tr>
<tr>
<td>Configuration Management</td>
<td>Describe what can be done to assure quality when specifications are applied in the field.</td>
</tr>
<tr>
<td>Supplier and Customer Controls</td>
<td>Mechanisms for working with Sequoia, Commonwell, DirectTrust, IHE</td>
</tr>
<tr>
<td>Testing and Evaluation methods</td>
<td>Describe the testing done and when it gets done by whom, etc.</td>
</tr>
<tr>
<td>Risk Management</td>
<td>Identifies what the risk are and how we attempt to mitigate them</td>
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</table>

Initial Brainstorm of topic ideas to be covered by the plan.

The VA has a quality improvement program. They are connected to 80% of the Sequoia Project systems. Focus on quality as the US CDI progresses. Could we get a presentation about this? They may be talking about it at HIMSS. They are doing this with real PHI, not just test data. Operationalizing the Carequality/Commonwell IG. Didi may be able to connect us to this effort.

Added clinical best practice content to document the quality requirements to get the information recorded so that the CDA document creation can happen in a quality way. Doing Quality Improvement Programs.

Does Testing and Evaluation overlap with Risk Management - should they be aligned or brought closer together.

Rick mentioned that we may want to move the Tooling and Evaluation chapter closer to the Risk Management chapter, and may even want to consider if they could be folded into a single chapter.
We moved them next to each other and agreed to revisit the merging once we begin to develop the content.

### 2019/01/02 Revisions

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
</table>
| Quality Culture for CDA and CDA Implementation Guides | Where we talk about the culture and commitment around quality that we aspire to promote and how we aim to support developing that and maintaining it.  
Roadmap plan for evolving the quality plan - Priorities over time.  
Identifies what the risk are and how we attempt to mitigate them |
| Quality Management | Describe the lifecycle of a standard and the quality control points within the cycle, what those check points consist of and who performs those checks. |
| Documentation & Tooling, Testing and Evaluation methods | List the set of supporting documents (current and planned). Describe what each one documents and the intended audience.  
Describe the testing done and when it gets done by whom, etc.  
Describe what can be done to assure quality when specifications are applied in the field. |
| Community Outreach | Mechanisms for working with HL7 Work Groups, ONC, Sequoia, Commonwell, DirectTrust, IHE, Da Vinci, etc.  
CDA Implementation-A-Thons |