CDX Vendor Conformance Process
Version 1.0

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AUTHORS

This document extensively re-uses, with PITO approval, content from BC PITO E2E Conformance Process, to ensure alignment and consistency for EMR Vendors in BC. The CDX Team responsible for CDX specific content/authorship are:

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Introduction

Purpose

The Electronic Medical Record (EMR) Conformance Process has been developed to validate that EMR software applications meet the conformance profiles defined by the CDX (Clinical Document eXchange) team. These profiles define guidelines and standards related to the consumption, use and display of data content delivered by the CDX distribution system.

Audience

Decommission of the IH Physician Office Integration (POI) and NH Clinical Information eXchange (CIX) is on the horizon. These distribution services are being completely replaced by the CDX distribution system.

The target audience for this document are EMR vendors planning/engaging in software changes in order to consume IH and NH Health Authority clinical documents and results from the new transport mechanism, the CDX distribution system.

Since this document addresses a fairly technical process, it is primarily directed at business analysts, software architects, developers and testers of EMRs.

Scope

At this time, the overall scope of conformance testing pertains solely to standards set for the utilization of CDX.

Conformance Documentation Structure

The documentation structure for conformance consists of three layers as follows:

1. Conformance Process Document

This document outlines the high-level processes that the EMR vendor will follow in asserting conformance to an in-scope specification. The actual processes that will be followed during conformance testing session of EMR systems that assert conformance is also outlined.

The Conformance Process document describes the end-to-end journey of the conformance process, as well as relevant policies and procedures.

2. Conformance Profile Documents

A Conformance Profile is a document that outlines the "testable" requirements that an EMR software must demonstrate, as it relates to specific use cases, clinical documents, or message types. The "testable" requirements of a Conformance Profile are derived from business, clinical and technical requirements and/or rules.

Each Conformance Profile establishes a specific marketable conformance capability (e.g., "CDA Level 3 Lab").

Each profile references the relevant portions of the BC eHR CDA Implementation Guide, and clearly outlines the conformance expectations in relation to the specification. This provides an opportunity to address potential ambiguities as well as to provide business guidance and clarity, particularly in situations where the specification's technical foundation (e.g. HL7) may create practical challenges in certain settings.

3. Target Specification

Target specifications are typically functional, content or interoperability specifications based on prevailing specification and/or interoperability paradigms. Examples include:

- HL7 International standards (e.g. HL7 CDA);
- Integrating the Health Enterprise (IHE) Interoperability Profiles;
- Canada Health Infoway pan-Canadian message specifications;
- Ministry of BC standards;
- Regional standards; and
- PITO EMR-to-EMR Data Transfer and Conversion (E2E-DTC) specification.

Note that at this time, only Conformance Profiles referencing the BC eHR CDA specifications will be available for Conformance assessment.

Conformance Profiles

Purpose

The purpose of a Conformance Profile is to group the requirements related to a specific process together into a logical unit. Conformance statements that are included in a conformance profile all relate to the specific technical and business expectations of an EMR system that wishes to participate in the specified CDX process.

Conventions

Use of Formal Language

Conformance Profiles make intentional use of the formal keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY and NEED NOT. Note that these key words

- **SHALL**: an absolute requirement;
- **SHALL NOT**: a prohibition against inclusion;
- **SHOULD** / **SHOULD NOT**: recommendation or best practice. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course; and
- **MAY** / **NEED NOT**: fully optional; can be included or omitted as the author decides with no implications.

Conformance Roles

Each Conformance Profile may include one or more roles. Such roles will either be defined within the profile or reference the following common roles:

- **Originator or Sender**: The system creating, originating or sending a particular document or message.
- **Recipient or Receiver**: The system receiving and processing a particular document or message.

Organization of Conformance Profile Documents

The organization of each conformance profile document is described in the following table:

Section / Field	Purpose
Profile Title	The official title of the Conformance Profile.
Profile Version	The official version of a particular Conformance Profile.
Release Date	The official release date as of which the Conformance Profile is available for use.
Contact Information	The person or group responsible for the Conformance Profile and any applicable contact details.
Profile Purpose	A brief summary of the purpose of the profile intended to be informative.
Profile Scope	A brief summary of the target scope for the Conformance Profile.
Intended Audience	The audience targeted for this Conformance Profile.
Documentation Links	To provide the source where the most current version of the Conformance Profile may be obtained.
Specification or Dependent Profile Reference(s)	Formally identifies specific versions of applicable specifications or profiles and, where applicable, sections of the referenced specification or profile.
Profile Overview	A brief summary of the profile.
Conformance Requirements	The formal conformance requirements imposed by the Conformance Profile.

The Conformance Requirements may vary based on the type of requirements addressed by a particular profile.

If a particular profile is focused on Clinical Document Architecture (CDA) messages the following subsections will be included:

Section / Field	Purpose
Section Conformance	Identifies the applicable CDA sections as well as the expected Conformance and Conformance Level for the section.
Conformance Requirements	Describes the conformance requirements that are specific to the conformance profile use case.

Conformance Process

Key Roles

Role	Purpose
CDX Conformance Team	This group consists of the CDX analysts, Health Authority knowledge area specialists, and other staff as required that will be facilitating and adjudicating the conformance process.
Vendor Lead	Primary vendor contact for coordination of the conformance process.
CDX Conformance Lead	Primary CDX contact for coordination of the conformance process.
Vendor Team	The vendor team supporting the conformance process.
Conformance Assessment Team	The team conducting a particular conformance assessment.
Juror	A member of the conformance assessment team. As a group jurors should include both technical and clinical individuals.

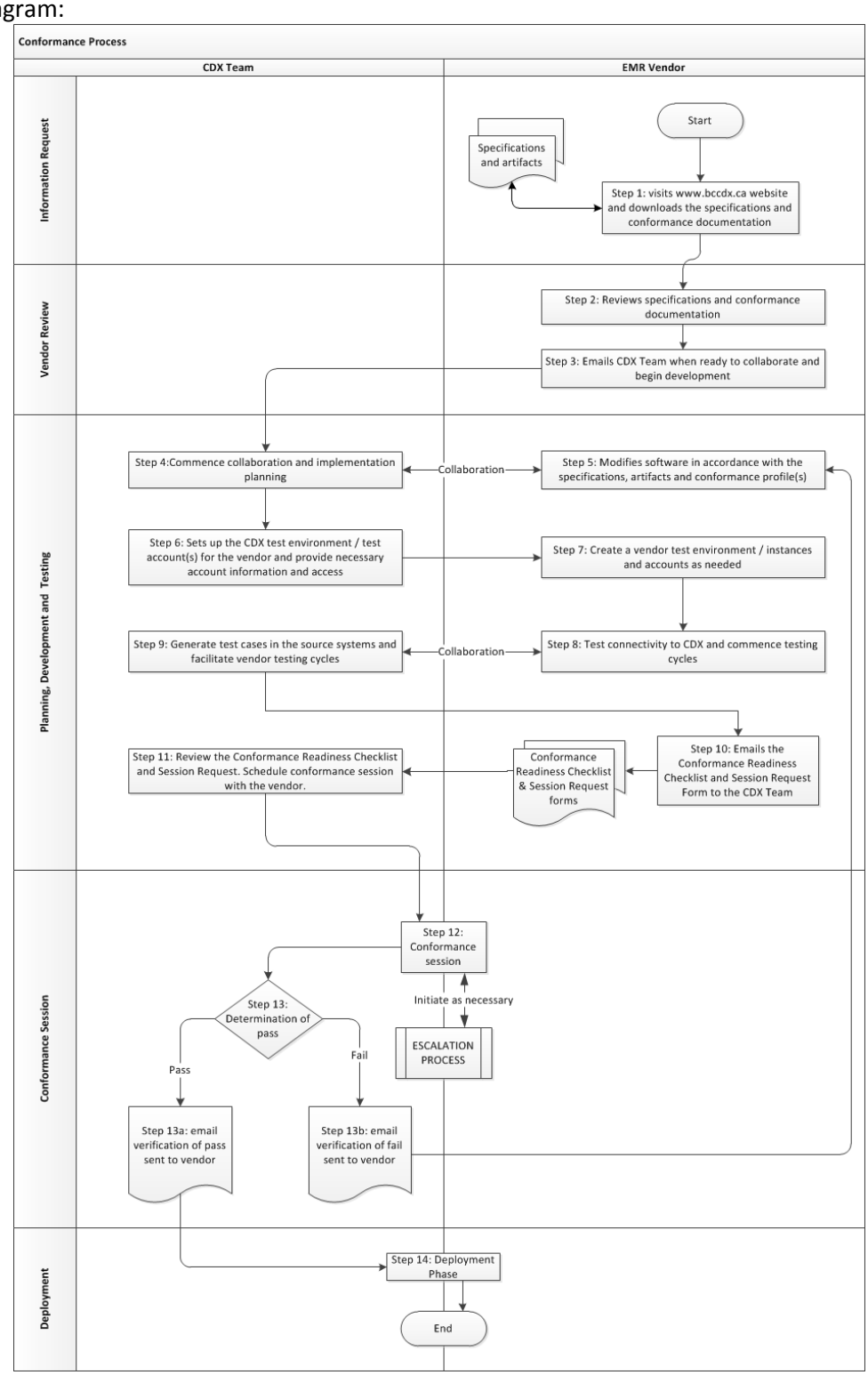
Conformance Process – High-level Overview

At a high level, the following processes must be completed in order to pass conformance against a Conformance Profile or Profiles:

Process Step	Trigger	Typical Timeline
Registration	Vendor interest	As appropriate
Vendor Review and Development	Vendor and/or key client requirements	(As appropriate timelines may vary)
Conformance Test Request	Vendor readiness	
Conformance Test	Readiness confirmed through checklist: Mutual schedule	Duration will depend on number of profiles to be included in a Conformance Testy cycle.
Deployment	Conformance test pass	As per vendor deployment cycle

Conformance Process – Workflow Diagram

Each process step contains multiple activities that are described in more detail in the following diagram:



Conformance Process – Steps to Follow

Vendor Information Request

Step	Activity Descriptions
1	Vendor team accesses the www.bccdx.ca website and downloads all of the necessary specifications, artifacts and conformance documents.

Vendor Review

Step	Activity Descriptions
2	Vendor team reviews the specifications, artifacts and conformance documents.
3	Vendor team emails the CDX Team when ready to collaborate and initiate software development
4	CDX Team commences coordination of collaborative effort.

Planning, Development and Testing

Step	Activity Descriptions
5	Vendor team initiates planning and software development lifecycle, and modifies EMR software in order to meet requirements of the targeted specifications, artifacts and conformance profile(s)
6	CDX team sets up the CDX test environment and test accounts, in order to provide the vendor with the necessary system access for the EMR to connect and consume messages from CDX
7	Vendor team creates EMR test environment/instance and test accounts as needed
8	Vendor team tests EMR system connectivity to the CDX system and commences testing cycle(s). Collaborate with CDX team for issue/test case remediation as necessary.
9	CDX team and source system Subject Matter Experts generate test cases in source systems to facilitate vendor testing cycles. Collaborate with Vendor team for issue/test case remediation as necessary.
10	When the EMR software development and QA/testing cycles are complete, the Vendor team e-mails the CDX team the "Conformance Readiness Checklist & Session Request form." Please note the following when ready for Conformance Session the request from the vendor SHALL include the following: 1. The profile(s) that the EMR software is conformant to, 2. The dates that the vendor is available for the Conformance Session, 3. A vendor statement declaring the readiness of the EMR software. If submitting a request for a **re**-Conformance Session, the request SHALL include items 1-3 noted above as well as: 4. A copy of the release notes identifying all defects/issues addressed from the previous conformance session, 5. A declaration from the vendor that all previously identified defects/issues have been remediated, and thoroughly tested.
11	CDX team reviews the "Conformance Readiness Checklist & Session Request form" submitted by the vendor, and proceeds to plan and schedule the conformance session with the vendor.

Conformance Session

Step	Activity Descriptions
12	**Conformance Session Overview** This process is anticipated to take between 1 ½ and 5 hours depending on: • the number of Conformance Profiles being tested in a single session, • whether the Conformance Profile(s) are at a CDA Level 1 (less time required) or a CDA Level 2 or 3 (more time required). **Preconditions:** A web conference and agenda for the conformance session will be provided to the teams participating. Additionally: • If necessary, the CDX Team will provide the vendor with additional login/account information to connect to the CDX web services, • The CDX Team will have test messages waiting in the CDX test environment for the vendor to request. **Session:** The Vendor team will facilitate a "walk-through" of the EMR software as follows: • Show the process an end user would go through to initiating the import/loading of clinical documents for each conformance profile, • Demonstrate how the CDA stylesheet is displayed for end user view, • Demonstrate how the data from the CDA header has been consumed into the EMR software, if applicable, • Demonstrate how the data from various CDA clinical document(s) templates, section templates and entries has been consumed into the EMR software, if applicable, • Demonstrate how the software complies with each of the conformance requirements in the Conformance Profile document(s). **Evaluation:** The CDX team will validate the conformance items and document any issues during the EMR walk-through at the Conformance Session.

Step	Activity Descriptions
13	**Determination of Pass:** After the conformance session has concluded, the CDX team will: • meet to document and review the results of the conformance, • decide if the EMR software passed, conditionally passed, or failed conformance, • notify the vendor team via e-mail within 5-10 business days from the date of the conformance session, whether the EMR software has passed, conditionally passed, or failed conformance. **Notification:** The Pass/Conditional Pass/Fail e-mail notification to the vendor will be sent within 5-10 business days from the date of the conformance session, and will include the following: • Vendor name, software name/version number, • Date of conformance session, • Specifications and Conformance Profile(s) evaluated, • In the case of a Conditional Pass or Fail, details of the identified issues/defects along with expected remediation requirements will be included. **Escalation Process:** If during the conformance session it becomes evident that certain requirements in the specifications/conformance documents were not clearly conveyed/interpreted, the CDX team and Vendor team may jointly decide to initiate the Escalation Process. • If possible, the conformance session will continue to completion, • If the issue is significant and continuation of the session is not possible, the session will be concluded, • The CDX team and Vendor team will collaborate to address and resolve the requirements issues, • Once the requirement(s) issue has been resolved, a subsequent Conformance Session will be rescheduled.

Deployment Phase

Step	Activity Descriptions
14	If, during the conformance session, there is a dispute over a requirement or the interpretation of a requirement, the Escalation Process may be activated • If possible, conformance testing will continue • If not possible, conformance testing will be suspended until the dispute is resolved

Policies and Procedures

Overview

Please note that these policies and procedures may change from time to time. Consult the latest version of this vendor conformance document available in the documents section of the www.bccdx.ca website.

Policy: Conformance Session Outcomes

Policy Item	Details
Policy Statement: Conformance Session Outcomes	As noted in the Conformance Session section above, the CDX team has authority to determine, and provide approval to indicate whether or not a Vendor has passed Conformance for a given Conformance Profile. The possible outcomes of a CDX conformance test are: • Pass – Based on a conformance evaluation, the vendor software meets all requirements of a conformance profile or profiles and no remediation is identified. • Conditional Pass – Some issues have been identified in the vendor software during the conformance evaluation for a conformance profile(s). The CDX team and the Vendor agree that the software or capability can be deployed but the vendor SHALL fix the identified issues and test them in the next release of the software or by the date identified by the CDX team. • Fail – Significant issues have been identified in the vendor software during the conformance session for a conformance profile(s). The vendor SHALL fix the issues and successfully pass a re-conformance session before a Pass can be granted. If there is any disagreement between the CDX team and the Vendor team about whether conformance has been satisfied, the escalation process policy may be initiated.
Reason for Statement	This policy is intended to clearly establish the potential outcome results of the conformance session process.
Roles & Responsibilities	This policy will be implemented by the CDX team.
Principles	Not applicable.
Definitions	Not applicable.
Procedures	Not applicable.

Policy: Communication & Publication of Conformance Results

Policy Item	Details

Policy Statement: Communication & Publication of Conformance Results	The publication of results will be in the form of a list of vendors that have Passed/Conditionally passed conformance. The list will be available on the www.bccdx.ca website.
	
	Results of the conformance session will be communicated as follows:
	• Notification to the vendor team via e-mail within 5-10 business days from the date of the conformance session, whether the EMR software has passed, conditionally passed, or failed conformance,
	• Confidentiality of the conformance session details will be maintained between the CDX team and the Vendor team,
	• Pass results will be published on www.bccdx.ca website, along with the following information:
	  ○ Vendor name, software name,
	  ○ Conformance status (Pass/Conditional Pass),
	  ○ Date of pass result,
	  ○ Specifications/Conformance Profile(s),
	• Details around Conditional Pass results will *not* be published,
	• Fail results will *not* be published.

Reason for Statement	This policy has been developed to clearly establish the extent to which conformance session results will be made communicated and made publicly available.
Roles & Responsibilities	This policy will be implemented by the CDX team.
Principles	Not applicable.
Definitions	Not applicable.
Procedures	Not applicable.

Policy: Escalation of Disputes

Policy Item	Details
Policy Statement: Escalation of Disputes	This policy has been developed to establish the escalation process which will be initiated to address disputes regarding the outcome/results of a Conformance Session. The authority for final decision in all such instances will be the Health Authority Directors for Clinical Information Systems.
Reason for Statement	This policy has been developed to clearly establish an escalation process to resolve CDX team/Vendor team disagreements on Conformance Session results. While the Conformance Session has been designed to be as objective as possible, there is the potential for subjective issues to arise which will require decision by the CDX team during the evaluation process. Since these decisions may impact the Pass/Conditional Pass/Fail status, it is possible that there may be disagreement about these decisions and the associated evaluation result. It is anticipated that usually such disagreements will generally be caused by differing interpretations about the intent of a Conformance Profile or the underlying specification(s).
Roles & Responsibilities	This policy will be implemented by the Health Authority Directors for Clinical Information Systems.
Principles	• The escalation process is to be used to resolve issues during the evaluation process in a conformance session. It is expected that most issues can be resolved through informal discussion between the stakeholders. Only those that cannot be resolved in such a manner will initiate the escalation process. • Although issues will be dealt with on a best effort basis, the targeted turnaround timeline from referral of an issue to the escalation process to final resolution should not exceed 10 business days, depending on complexity.
Definitions	• Issue: The term "issue" as used in the Escalation Process refers primarily to a question of interpretation of the conformance requirements or underlying specifications, and may include questions regarding methods of implementation of the standards in software.
Procedures	A Vendor or potential implementer of a Conformance Profile may refer an issue to this process. • The referring person will document the issue, noting and describing the section of the Conformance Profile (and/or underlying specification) that is of concern, and describe in detail the conflicting interpretation(s).

Policy Item	Details
	• The escalation referral will be submitted via e-mail to the CDX team at bccdx@interiorhealth.ca. • The CDX Lead will review the request and provide a written summary and opinion on the issue to the CDX Management Team. • Should the CDX Management Team determine that additional feedback is required from the stakeholder partners, that request will be carried through by the CDX Management Team. The CDX Management team will provide written direction on the issue to the CDX Team. • Should further consultation be required, the CDX Team will consult with appropriate stakeholders and standards experts as appropriate based on the issue raised. • Having considered the comments received, the CDX Management Team will render a final decision as to the interpretation of the requirements. The decision rendered will be the final disposition of the issue. • The CDX Lead will communicate the decision to all vendors via e-mail as appropriate. • The CDX Team will ensure that the relevant specification(s) and associated conformance profile(s) are updated as necessary.

Policy: Issue/Defect Rating Criteria

Policy Item	Details
Policy Statement: Issue/Defect Rating Criteria	A rating criteria in the form of a severity matrix will be applied to the decision process for all issues/defects identified in the EMR software being evaluated during the conformance session. The severity matrix and associated definitions can be found below.
Reason for Statement	The criteria established under this policy are intended to support dialog about issues/defects identified while evaluating the software during the conformance session.
Roles & Responsibilities	This policy will be implemented by the CDX team.
Principles	Not applicable.
Definitions	Not applicable.
Procedures	Not applicable.

Conformance Evaluation – Severity Matrix for Issues/Defects		
Severity Level	**Result / Definition**	**# Allowable**
Critical	• Critical issues, by definition, cannot be deferred and therefore will result in the failure of a conformance evaluation. An issue/defect is noted related to a specific conformance item which is considered by the CDX team to be critical impact to patient care, clinical business processes, and/or preservation of clinical data.	0 Critical
High	• The CDX Team determines that there is a satisfactory work-around for an issue, but it is not an acceptable long-term solution. • Vendor agrees to fix the issue for the next release of their software. An issue/defect is noted related to a specific conformance item which is considered by the CDX team to be high impact to patient care, clinical business processes, and/or preservation of clinical data.	3 High
Medium	• System produces one-time errors that cannot be re-created by vendor testers or during conformance evaluation. An issue/defect is noted related to a specific conformance item which is considered by the CDX team to be medium impact to patient care, clinical business processes, and/or preservation of clinical data.	5 Medium
Low	• Errors are deemed to be inconsequential to the use case(s) targeted by the Conformance Profile. An issue/defect is noted related to a specific conformance item which is considered by the CDX team to be low/minor, such as cosmetic issues which do not impact in any substantive way to patient care, clinical business processes, and/or preservation of clinical data.	Unlimited

Policy: Release Management Policy

Policy Item	Details
Policy Statement: Release Management	Our current POI/CIX release management policy specifies that we will provide 6 months notice for major revisions and upgrades, and 90 days notice for enhancements, updates or value set changes. The CDX service provides increased functionality, and therefore the current policy and timelines is under review. It is anticipated that new terms and timelines around release management will be established, where adjustments may occur based upon the following criteria: • Critical – critical risk exists, and change must occur with a quick turnaround, • Major – CDX or source system software change, revisions to messaging standard(s), new content and/or templates, • Medium – Regular enhancements and/or updates, • Minor – Value set or similar change (e.g. LOINC code change/addition). Until the new policy and timelines are determined, the current POI/CIX release management and policy will continue to be followed, with the exception of where critical risk exists. In these urgent instances, the issue will be addressed on a case-by-case basis, with appropriate discussion/communication with EMR vendor reprentatives prior to any changes being implemented. Note that system changes may result in updates to the conformance process and/or conformance profiles.
Reason for Statement	This policy has been developed to establish the CDX change management policy and timelines.
Roles & Responsibilities	This policy will be implemented by the CDX team.
Principles	Not applicable.
Definitions	Not applicable.
Procedures	To be determined.

Policy: Conformance Audits and Inspections

Policy Item	Details
Policy Statement: Conformance Audits & Inspections	Upgrades and changes to EMR software may trigger a conformance compliance audit. Additionally, reports of non-compliance from clinical stakeholders and EMR software end-users may also trigger a conformance compliance audit. If a conformance audit is determined necessary by the CDX Management Team, the vendor will be contacted to schedule re-conformance of the appropriate Conformance Profiles. The timelines for completion of Conformance Profiles within these circumstances shall be determined based upon the severity and clinical risk of the issue. Re-conformance shall not exceed 3 month from the date of notification to the vendor. Failure to comply with an audit/inspection re-conformance request may result in notification to subscribed users, and possible suspension of distribution service depending on severity of the issue.
Reason for Statement	This policy has been developed to establish the criteria for Conformance Audits & Inspections.
Roles & Responsibilities	This policy will be implemented by the CDX team, with support from the CDX Management team.
Principles	Not applicable.
Definitions	Not applicable.
Procedures	To be determined.

Policy: Re-Conformance Limits

Policy Item	Details
Policy Statement: Re-Conformance Limits	At this time there are no provisions for limiting the number of re-conformance sessions required by a vendor, or for establishing penalties for excessive remediation and re-conformance cycles. This may be added in future.
Reason for Statement	Not applicable.
Roles & Responsibilities	Not applicable.
Principles	Not applicable.
Definitions	Not applicable.
Procedures	Not applicable.

Appendix A – Contact Information

Contact Group	Contact Details
CDX Team	The CDX Team can be reached via e-mail at: bccdx@interiorhealth.ca
CDX Management Team	The CDX Management Team can be reached via e-mail at: bccdx@interiorhealth.ca

Appendix B – Information Resources

Information Needed	Contact
CDX Distribution System documentation, including: • xsd files to generate .net objects, • Specifications based upon HL7 v3 universal interactions for: Document Retrieval Messages: • RCMR_IN000031UV01 • RCMR_IN000032UV01 • RCMR_IN000029UV01 • RCMR_IN000030UV01 • MCCI_IN1000001UV01 Document Submission Interactions: • MCCI_IN000002UV01 • RCMR_IN000002UV01 Registry Query Interactions • PRPM_IN406010UV • PRPM_IN406110UV • PRPM_IN306010UV • PRPM_IN306010UV • PRPM_IN306011UV Transmission Wrapper: • MCCI_MT000100UV01	This specification is available upon request by contacting: bccdx@interiorhealth.ca
BC eHR CDA Implementation Guide – Provincial Standard	This implementation guide is available upon request by contacting: bccdx@interiorhealth.ca

Appendix C - Conformance Readiness Checklist

Prior to submitting a Conformance Session Request, please complete the following checklist to determine readiness for a conformance session.

#	Conformance Readiness	Yes	No	N/A
1	Conformance Profile(s), all associated specifications and any applicable test data have been downloaded and reviewed by the vendor development team. Please itemize the files reviewed:			
2	The required capabilities have been engineered into the software.			
3	Internal unit and system testing have been successfully conducted.			
4	A software instance on which conformance demonstration and evaluation can occur has been created.			
5	For conformance of an EMR that is currently deployed, provide the current version of the Vendor system and the number of sites deployed to.			
6	If this is a re-conformance session request, the required remediation changes have been engineered into the version of software ready to be evaluated. For Conformance Tests for a vendor that previously received a conditional pass or that have previously failed the identified defects and.			

Appendix D - Conformance Session Request Form

Vendor Name	
Contact Person	
Telephone	
Email	
Product	
Version	
Conformance Profile(s) Targeted	
Notes	
Earliest Date Ready for Testing	
Preferred Test Window	
Comments	
Please attach completed Conformance Session Readiness Checklist	