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|  |
| Health eDecisions  CDS Guidance Service  (Use Case 2) |
| Technical and Standards Design Document |
|  |
| Version #.#  *<<Date>>* |
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**Version History**

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| --- | --- | --- | --- |
| **Version Number** | **Revision**  **Date** | **Author** | **Description of Change** |
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# 1.0 Introduction & Purpose

***Section Description****: In this section, give a brief overview of the initiative, and what the design document will provide. The Technical and Standards Design Document should act as a guide for all subsequent technical and standards development activities in the Standards & Harmonization Phase. Include the black text below to clearly detail the Purpose.*

*Note - The completed Use Case and Functional Requirements document should be heavily referenced when completing this document.*

*Overview the following for the initiative, derived from the Use Case:*

* *Scope*
* *Assumptions and Conditions*
* *Scenario*
* *Actors*
* *Exchanges (Transaction and Content)*
* *Data*

The goal of the Health eDecisions (HeD) initiative is to identify, define and harmonize standards that facilitate the emergence of systems and services whereby shareable Clinical Decision Support (CDS) interventions can be implemented via:

* Standards to structure medical knowledge in a shareable and executable format for use in CDS (Use Case 1: “CDS Artifact Sharing”), and
* Standards that define how a system can interact with and utilize an electronic interface that provides helpful, actionable clinical guidance (Use Case 2: “CDS Guidance Service”)

This document will focus on the CDS Guidance Service Use Case. This Use Case defines the requirements for the interfaces for sending patient data and receiving CDS guidance. This Use Case has one scenario: Requesting Clinical Guidance From A CDS Guidance Supplier. Further details can be found within the Use Case document at the following URL: <http://repository.siframework.org/share/proxy/alfresco/api/node/content/workspace/SpacesStore/5810392a-e5bb-494b-b4cf-4aedb8fe358d/SIFramework_HeD_UC2_CDSGuidanceService_v1.0.docx?a=true>

The Functional Requirements & Data Set Specifications can be found at the following URL: <http://repository.siframework.org/share/proxy/alfresco/api/node/content/workspace/SpacesStore/8b8e98c1-73d1-4020-9704-5e9e6afc949f/SIFramework_HeD_UC2_FRDS_v1.0.xlsx?a=true>

The purpose of the S&I Technical and Standards Design Document is to:

1. Provide granular-level of technical detail to the business & functional requirements outlined in the Use Case
2. Document an overall technical & standards design approach for the initiative
3. This document and its underlying standards evaluation documents are intended to act as an input to the development of detailed solution artifacts (e.g. Implementation Guidance, updates to standards, etc.)

# 2.0 Technical Analysis of Use Case Functional & Data Requirements

***Section Description****: This section is to show a detailed technical analysis of the Functional (Information Interchange & System Requirements) and Data Requirements outlined in the Use Case*

## 2.1 In-Scope Requirements Analysis

***Section Description****: Use this section to expand the in-scope Use Case requirements to include technical details. The IDs within this section are taken from the consensus approved Use Case.*

## 2.1.1 Information Interchange Functions

***Section Description****: For the Use Case information interchange requirements include the following technical details:*

* *Assign roles to technical actors (sender, receiver, and responder.) A system should be listed once per role (e.g. if a system acts as both a sender and receiver it should be listed twice in the table, once for each).*
* *Define exchange type: push (with or without response), pull (query-response), publish, subscribe, etc.*
* *Document the data requirements for exchange at the level similar to the “Data Objects”( column E) of the Common Actions within the* [*Core Matrix*](http://wiki.siframework.org/file/view/ONC-SI-Simplification-Core-Matrix-v2_3-20121211.xlsx/391565188/ONC-SI-Simplification-Core-Matrix-v2_3-20121211.xlsx)*. There should be a direct link between the requirements listed in this column to the requirements contained in* *Table 3: Data Requirements*
* *Add supporting exchanges not listed in UC, e.g., check patient consent, if within scope*
* *Additional Supporting Exchanges defined as a pre-requisite exchange which must be implemented to successfully implement the Use Case*
* *Could also include error messages or acknowledgement if defined as a part of the Use Case*
* *Technical Feasibility considerations:*
* *Are there existing approaches that could be used that is widely accepted?*
* *If not, what is the projected time & effort to make this happen?*

| **ID** | **System** | **Functional Role** | **Technical Role** | **Information Interchange Requirement Name** | **Exchange Type** | **Additional Supporting Exchanges** | **Technical Feasibility** | **Include in Technical Design (Y/N)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| II01 | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | CDS Guidance Requestor | Sender | CDS Request (Patient Data and Potentially Contextual Information) | Query/Response  Synch/Asynch | None | Feasible (e.g., DSS)  (DSS currently only supports synchronous) | Y  (anticipate supporting only synchronous) |
| II02 | CDS Service | CDS Guidance Supplier | Receiver | CDS Request (Patient Data and Potentially Contextual Information) | Query/Response  Synch/Asynch | None | Feasible (e.g., DSS)  (DSS currently only supports synchronous) | Y  (anticipate supporting only synchronous) |
| II03 | CDS Service | CDS Guidance Supplier | Sender | CDS Response (Clinical Guidance and/or Other Response Elements) | Query/Response  Synch/Asynch | None | Feasible (e.g., DSS)  (DSS currently only supports synchronous) | Y  (anticipate supporting only synchronous) |
| II04 | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | CDS Guidance Requestor | Receiver | CDS Response (Clinical Guidance and/or Other Response Elements) | Query/Response  Synch/Asynch | None | Feasible (e.g., DSS)  (DSS currently only supports synchronous) | Y  (anticipate supporting only synchronous) |

Table : Information Interchange Requirements

## 2.1.2 System Functions

***Section Description****: For the Use Case System Requirements, determine if each is necessary for the technical design and within scope of interoperability, e.g., necessary pre-condition. Please note, technical design may or may not include system requirements based on the scope of the initiative and if the system requirements are in support of interoperability functions. For this reason, the last column is included in this table.*

| **ID** | **System** | **System Requirement** | **Technical Feasibility** | **Include in Technical Design (Y/N)** |
| --- | --- | --- | --- | --- |
| S01 | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | Generate a CDS Request with Patient Data and Potentially Contextual Information | Feasible (multiple potential data models and constraint mechanisms available – to be discussed as part of the UCR Crosswalk) | Y |
| S02 | CDS Guidance Requestor’s System (e.g., Clinical Workflow System) | Receive a CDS Response Containing Clinical Guidance and/or Other Response Elements | Feasible (multiple potential data models and constraint mechanisms available – to be discussed as part of the UCR Crosswalk) | Y |
| S03 | CDS Service | Process a CDS Guidance Request Containing Patient Data and Potentially Contextual Information | Feasible (multiple potential data models and constraint mechanisms available – to be discussed as part of the UCR Crosswalk) | Y |
| S04 | CDS Service | Generate a CDS Response with Clinical Guidance and/or Other Response Elements | Feasible (multiple potential data models and constraint mechanisms available – to be discussed as part of the UCR Crosswalk) | Y |

Table : System Requirements

## 2.1.3 Data Requirements

***Section Description****: For the Use Case data requirements, add data type if applicable to indicate vocabulary, terminology, value set and/or code set.*

* *Alternative value and/or code sets can be identified and enumerated in the below table*
* *The table’s content should be leveraged to develop the initiative’s data dictionary*
* *Per initiative requirements, the below table can be duplicated for each transaction in a separate sub-section, 2.1.3.x*

| **ID** | **Data Element Set/ Section** | **Data Element** | **Data Type** | **Cardinality** | **Optionality** | **Value and/or**  **Code Sets** | **List applicable Information Interchange IDs** | **Technical Feasibility** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| D01 |  |  |  |  |  |  |  |  |
| D02 |  |  |  |  |  |  |  |  |

Table : Data Requirements

## 2.2 Out-of-Scope Requirements Analysis

***Section Description:*** *Use this section to cover the assumptions and conditions excluded from the primary exchange documented in the Use Case. Requirements in this section are at the boundary of the Use Case activity and may not be pertinent for the flows, but could have considerations for architecture or implementation. Include columns for:*

* *Refer to the types in the Core Matrix:* [*http://wiki.siframework.org/file/view/ONC-SI-Simplification-Core-Matrix-v2\_3-20121211.xlsx/391565188/ONC-SI-Simplification-Core-Matrix-v2\_3-20121211.xlsx*](http://wiki.siframework.org/file/view/ONC-SI-Simplification-Core-Matrix-v2_3-20121211.xlsx/391565188/ONC-SI-Simplification-Core-Matrix-v2_3-20121211.xlsx)*.*
* *Considerations for infrastructure requirements and architecture/implementation options*

*For the requirements listed below, please assign an ID in the far-right column* ***only when the requirement is required as part of the technical solution.*** The naming structure for these IDs should follow the ID structures used above and should be dependent on what type of requirement from above it aligns with: *for example if an assumption requires an ID the ID would begin with A01, a pre- condition would be PRC and a post condition would be POC.*

| **Requirement Type** | **Requirement Details** | **Reason for Excluding** | **Consider When Defining Infrastructure Requirements (Y/N)** | **Consider When Defining Implementation Options (Y/N)** | **Consider When Designing Technical Architecture (Y/N)** | **If requires inclusion in design: User-generated ID** |
| --- | --- | --- | --- | --- | --- | --- |
| Assumption | The CDS Guidance Requestor determines when to make a guidance service call. | Functionally Out of Scope | N | N | N |  |
| Assumption | This is a stateless CDS service. For purposes of obtaining guidance, the CDS Guidance Requestor should NEVER assume that the service is stateful or able to utilize historical requests to provide guidance. However, the CDS Guidance Supplier may store the data for auditing and other operational reasons. | Stateful CDS services are functionally out of scope | N | N | N |  |
| Assumption | The CDS Guidance Supplier provides sufficient requirements to the CDS Guidance Requestor for the CDS Guidance Requestor to determine the data that must be sent to the supplier during a guidance request. |  |  |  |  |  |
| Assumption | The CDS Guidance Supplier is responsible for verifying the unique response IDs to ensure that CDS Guidance Requestors can communicate unambiguously with the service and that the meaning of the response ID is consistent for historical and current CDS interactions. |  |  |  |  |  |
| Assumption | The role of the CDS Service Integrator and the associated functions (such as implementation) are handled outside of this Use Case, prior to the CDS Guidance Requestor sending a request. |  |  |  |  |  |
| Assumption | User agreements (trust relationships) are in place between the Guidance Requestor and Guidance Supplier, if required. |  |  |  |  |  |
| Assumption | The CDS Guidance Requestor is responsible for *not* sending identifiable protected health information unless the appropriate agreements are in place to do so. |  |  |  |  |  |
| Assumption | If a CDS Guidance Supplier receives identifiable protected health information that it expects (based on user agreements), then it will comply with legal and regulatory requirements for privacy and security for all relevant jurisdictions (including, but not limited to, HIPAA, state-level requirements, etc.). |  |  |  |  |  |
| Assumption | The CDS Guidance Supplier will make clear its policy for retaining or sharing any data received from the CDS Guidance Requestor, and it will comply with this stated policy. |  |  |  |  |  |
| Assumption | These transactions may be conducted in either a synchronous or an asynchronous manner. |  |  |  |  |  |
| Assumption | Patent and intellectual property protection are addressed by participants. |  |  |  |  |  |
| Assumption | A regulatory framework exists and will include appropriate classifications and reviews by FDA, CDC, CMS and other organizations. |  |  |  |  |  |
| Assumption | A liability framework exists to manage liability. |  |  |  |  |  |
| Assumption | A certification mechanism for compliance with the standard is in use. |  |  |  |  |  |
| Assumption | Conformance to the standards/solution described in this Use Case may occur directly between a CDS Guidance Requestor and CDS Guidance Supplier, or through an intermediary party (e.g., for interface, model, or terminology mapping). |  |  |  |  |  |
| Assumption | Conformance will be addressed further by subsequent phases of S&I Framework and may be specified at multiple levels, e.g., at the interface, model, and terminology levels. |  |  |  |  |  |
| Pre-Condition | The CDS Guidance Requestor’s system is pre-configured to identify triggers to request clinical guidance. |  |  |  |  |  |
| Pre-Condition | The CDS Guidance Requestor’s system is pre-configured to receive the clinical guidance data and integrate it into the system. |  |  |  |  |  |
| Pre-Condition | The CDS Service Integrator is able to identify the type of CDS Guidance Service for specific scenarios (e.g., immunization reminders). |  |  |  |  |  |
| Pre-Condition | CDS Service Integrator is able to identify the end-point address for making the request for CDS Guidance. |  |  |  |  |  |
| Pre-Condition | The CDS Guidance Requestor’s system is aware of and able to supply the input parameter values (the clinical information and context). |  |  |  |  |  |
| Pre-Condition | The CDS Guidance Requestor’s system is able to map to/from the terminology and content format standards specified in the standards selected by the Health eDecisions Initiative, either natively or by way of a third party (which might be the CDS Guidance Supplier itself). |  |  |  |  |  |
| Pre-Condition | The CDS Guidance Supplier is able to formulate non-guidance components of the response (such as error messages). |  |  |  |  |  |
| Pre-Condition | The CDS Guidance Requestor is able to properly process the defined non-guidance components of the response (such as errors in submitted data, additional information required, etc.). This would include things such as notifying technical staff of operational / data format errors, and notifying user, if appropriate, of the need for additional data. |  |  |  |  |  |
| Post-Condition | The CDS Guidance Supplier has sent Guidance to the CDS Guidance Requestor’s system. |  |  |  |  |  |
| Post-Condition | The CDS Guidance Requestor’s system has received the Guidance sent by the CDS Guidance Supplier. |  |  |  |  |  |
| Post-Condition | The Guidance returned by the CDS Guidance Supplier is available for display and/or action within the CDS Guidance Requestor’s system. |  |  |  |  |  |

Table : Out-of-Scope Requirements

## 2.3 Solution Diagram

***Section Description:*** *Use this section to depict the overall solution diagram which represents the solution. Leverage the overall initiative workflow & Use Case diagrams to map potential standards pictorially.*

*The below example is specific to the esMD initiative, and the components included may vary per initiative.*

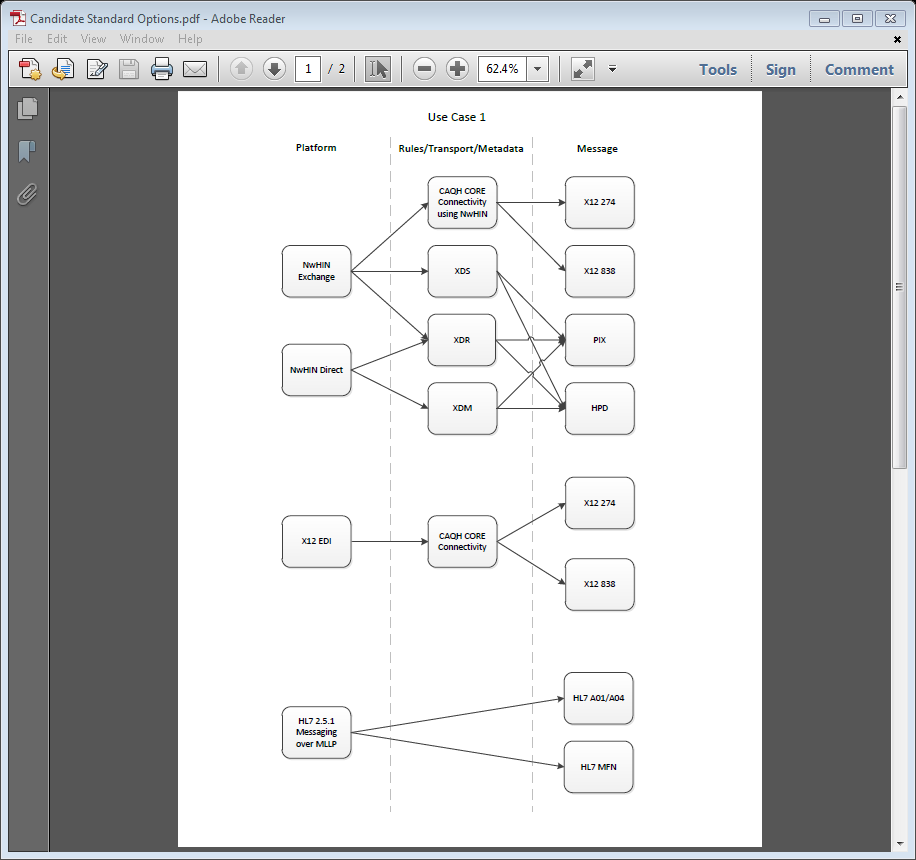
**

Figure : Solution Diagram

## 2.4 Data Model/Content Approach

***Section Description:***  *Use this section to describe the proposed approach for leveraging or developing informing components of, or entire, data models or other content needed for the initiative transactions. This could be represented using UML diagrams as appropriate. The content in section 2.2.3 should be used to develop this section.*

* *Due to the requirements of a particular initiative, this section can be optional for inclusion.*

# 3.0 Solution Analysis

## 3.1 Identify Existing Solutions or Modules for Re-Use

***Section Description:*** *This section will reference, via link to wiki, to the Candidate Standards list that was developed during the Pre-Discovery & Use Case development phases. When working through this section with the community the candidate standards list should be reviewed to ensure there are no missing standards. This section can also be used to capture other initiative work efforts that should be evaluated and potentially leveraged when developing the solution.*

***Suggested format:*** *List any standards or other content identified in addition to the initial candidate standards*

## 3.2 Evaluate Candidate Standards

***Section Description:*** *There are two major steps for completing this section:*

1. *Using the candidate standards list as a starting point pull in all of the standards to the table below and document the design relevance.*
2. *For those standards relevant to the design use the standards analysis matrix to evaluate each standard against the HITSC-recommended criteria for maturity, implement-ability, etc. (See* [*Standards Analysis template*](http://wiki.siframework.org/file/view/General%20SI%20Framework%20Standards%20Analysis.xlsx/297940330/General%20SI%20Framework%20Standards%20Analysis.xlsx)*) Please note a link to the completed Standards Analysis Matrix on the wiki for the initiative should be included within this section.*

***Section Format: 1)*** *Table of candidate standards and design relevance. 2)* [*Standards Analysis template*](http://wiki.siframework.org/file/view/General%20SI%20Framework%20Standards%20Analysis.xlsx/297940330/General%20SI%20Framework%20Standards%20Analysis.xlsx) *that has been populated, reviewed with community, uploaded to the wiki and linked within this section*

| **Standard** | **Relevant to Design?** | **Description** |
| --- | --- | --- |
| *Laboratory Results Interface Implementation Guide* | *Yes* | *The LOI solution will need to take into account the solution for LRI as that documents the follow-on processes after LOI is executed.* |
| *HL7 2.5.1. Messaging Standard* | *Yes* | *This is a messaging standard that should be considered in support of LOI requirements.* |
| *LOINC* | *No* | *LOINC will be part of the transaction, but does not need to be taken into consideration for solution design.* |

Table : Design Relevance of Candidate Standards

*<<Include snapshot/reference of HITSC-evaluation criteria matrix>>*

# 4.0 Solution Mapping

## 4.1 UCR-Standards Crosswalk & Gap Identification

***Section Description:***  *Use this section to map the technically feasible requirements from section 2.0 to the standards in 3.2. With each requirement document the standards mapping and any known gaps. This table is the UCR-Standards Crosswalk. Please note the IDs captured in this table originate from the tables in sections 2.2 & 2.3.*

| **ID** | **Standard** | **Standards Gap** |
| --- | --- | --- |
| *II01* | *HL7 Messaging Standard Version 2.5.1* |  |
|  |  |  |
|  |  |  |

Table : UCR-Standards Crosswalk

## 4.2 Solution Plan

***Section Description:*** *Use this section to capture recommendations around extension, modification, or creation of new or existing standards or profiles to close any gaps between selected standards and functional or technical requirements. This becomes the Gap Mitigation plan. A high level summary of the design to complete initiative implementation guide(s) and/or fill gaps through SDOs should also be included within this section.*

***Suggested format:*** *Table to document Recommendations*

| **ID** | **Recommendation** | **Summary of Design Solution** | **Incorporate into Final Design (Y/N)** |
| --- | --- | --- | --- |
| *II01* | *Populate with: extension, modification, or creation of new or existing standards or profiles* | *Add additional details about how this would fit into an overall solution and what implementation guidance (e.g. constrain use of a data element to specific values) would be required to meet requirement* | *This determination should include whether or not the complexity of the recommendation and/or design solution is at an acceptable level.* |
|  |  |  |  |
|  |  |  |  |

Table : Recommendations for Design Solution

## 4.2.1 Summary of Potential Changes to External Artifacts and Corresponding Ballot or Approval Process Considerations

***Section Description:*** *This section will be used to summarize what changes may be required to standards or documentation owned by external organizations. Populate the “Standard or External Guidance Artifact” with all standards relevant to accepted design solutions (4.2 Table with “Y” in “Incorporate into Final Design” column) and the “Summary of Required Changes” column with all applicable changes for that artifact as identified in table 4.1. Please note that each relevant standard should be listed once, and all required changes for that standard should be grouped into a single cell under “Summary of Required Changes”. Leveraging information in the candidate standards list, other informally documented information (e.g. SDO Engagement Plan that is typically developed by SDS team), and community expertise populate the remaining columns “Owning Organization”, “Organization’s Ballot Process, Timelines and other Considerations” and “Organization Contact”*

***Suggested format:*** *Below table*

| **Standard or External Guidance Artifact** | **Summary of Required Changes** | **Owning Organization (e.g. the SDO name)** | **Organization’s Ballot Process, Timelines and other Considerations** | **Organization Contact** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table : Summary of External Artifacts Requiring Work

## 4.2.2 Expected Artifacts to Support Solution Plan

***Section Description:*** *List all relevant artifacts required to support the approach detailed in this design document within the Standards & Harmonization phases of the S&I Framework. This list will be refined with initiative-specific content, in addition to general S&I artifacts. Some examples:*

| **Artifact Name** | **Description** | **Location** |
| --- | --- | --- |
| Standards Analysis Matrix | Facilitates the evaluation of standards according to the following: 1) Maturity of Standards and Technology, and 2) Deployment/Operational Complexity and Market Adoption; the process includes evaluation of “broad” and “detailed” criteria. This is based on FACA recommendations on evaluation criteria developed by HITSC’s NwHIN WG. | Included above (see 3.2 Evaluate Candidate Standards) |
| Standards-UCR Crosswalk | Used as a means to capture the applicability of candidate standards to the user scenarios, use cases and requirements documented in the Use Case. | Included above (see 4.1 UCR-Standards Crosswalk & Gap Identification) |
| Extension, modification, or creation of new or existing standards or profiles | Identifies standards or profiles that will need to be modified in order to support or align with the initiative’s solution. It also documents the owning organization and corresponding approval process for getting changes incorporated, which can be a factor in determining if standard is worth including within the solution. | Included above (see 4.2.1 Summary of Potential Changes to External Artifacts and Corresponding Ballot or Approval Process Considerations) |
| Initiative Data Dictionary (previously referred to as “High-Level Data Model”) | Captures data elements, data types, and cardinality that will be required to support the initiative’s solution. | Not yet available |
| Implementation Guidance | Provides clear, unambiguous recommendations and guidance to the commercial vendor or open-source communities. The IG is intended to address the scope and needs of an Initiative. | Not yet available |
| Requirements Traceability Matrix (RTM) | The RTM document is created after the completion of the Use Case and updated throughout the lifecycle of the initiative. Completion of this document will not have any direct impact on the RTM, but the Implementation Guidance (IG), which is developed based on the analysis performed within this document, will inform the population of IG conformance statements within the RTM. | *Add link to file on wiki, if applicable* |

Table : Expected Artifacts

# 5.0 Technical Risks, Issues and Obstacles

***Section Description****: The Risks, Issues and Obstacles section lists the concerns that might interfere with meeting the proposed Technical and Standards Design.*

# Appendices

*The content of this section varies depending on the needs brought forth by the Community. Some Design Documents may have appendices that are specific to their content and issues. The appendices listed below are suggested for inclusion.*

## Appendix A: References

| **Document Name** | **Description** | **Location** |
| --- | --- | --- |
| *<Document Name and Version Number>* | *<Document description>* | *<URL or Network path where document is located>* |
|  |  |  |

Table : References

## Appendix B: Key Terms

| **Term** | **Definition** |
| --- | --- |
| *<Insert Term>* | *<Provide definition of term and acronyms used in this document.>* |
|  |  |
|  |  |

Table : Key Terms