

FOR INTERNAL USE

NHS SCOTLAND
SCCRS HR-HPV HL7 INTERFACE
INTERFACE CONTROL DOCUMENT (ICD)

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1 Introduction

1.1 Purpose

The purpose of the Interface Control Document (ICD) is to:

- Provide a full technical specification of the interface, providing the requirements for the low-level design activity
- Identify the responsibilities for the design, implementation, testing and acceptance of the interface
- Specify the test requirements for the interface.

1.2 Scope

In Scope

- Provide a definition for an interface that will allow HR-HPV Results to be received into SCCRS.

Out of Scope

- Exception management capabilities in the middleware to handle unexpected situations.

1.3 Target Audience

The target audience comprises:

- Account Architecture Authority
- Technical Architect responsible for the high-level design of the interface
- Delivery Manager
- Requirements Manager/Business Analyst
- Test Manager
- All those responsible for the review and approval of the Solution at any level
- All members of the delivery project team with a responsibility for the development, implementation and testing of the Solution.

1.4 Referenced Documents

List all documents relevant to the ICD e.g.: the Architecture and the DFD (Business Interfaces).

#	Name	Version	Date
1	SCCRS HL7 Message Service Solution Definition Document	1a	01/12/2017

1.5 Definitions, Acronyms and Abbreviations

This is the glossary of terms used in the ICD. Either add all terms into the table or replace the table with a cross reference to the project Glossary and add the Glossary document to section 1.4 as a Referenced document.

The following terms are used within this document only.

Term	Description
HL7	Health level 7 is an industry standard in the health service industry for electronic message interface between systems. V2.x is the most widely available in use. Other versions include HL7 V3 and HL7 FHIR
SCCRS	Scottish Cervical Call-Recall Screening System This refers to an application developed by the NHS in Scotland to manage the Scottish Cervical Screening Program.
ACK	ACK is shorthand in HL7 for a positive acknowledgement of a message when it is received or processed successfully.
NACK	NACK is shorthand in HL7 for a negative acknowledgement of a message. It signifies that something went wrong.
HR-HPV	High Risk Human Papilloma Virus
LIS	Laboratory information system. Sometimes also called the Laboratory information management software (LIMS)
Middleware	Within healthcare/result testing, middleware is a common term for the application that amongst other things provides connectivity between different lab hardware generating results (analysers), processes/transforms the results and sends the results to a receiving system(LIS).
MLLP	Minimal Low-Level Protocols To allow systems to communicate over tcpip, protocols require to be established between a sender and receiving system. Typically, this will be all of the following: - Ip, Port, start frame protocol, End frame protocol, containing protocol, record break protocol
CSR / CSR ID	Cervical Screening Request / Cervical Screening Request ID Or SCCRS Number This is the sample identifier used throughout SCCRS. When the sample is taken initially by the health care professional they fill out a Cervical Screening Request (CSR) form. This generates the unique CSR ID for the sample in SCCRs. As it is generated a label is printed and applied to the sample container. Note: The CSRID is often printed with additional check digits.
Lab No	When a sample is booked into a LAB a unique Laboratory Number (Lab No) is generated. As it is generated a label is printed and applied to the sample container. The Lab No was introduced during the SCCR HPV project. It replaces two separate identifiers that were previously used "Virology Number" and "Cytology Number"
Virology ID	This ID was previously generated when a sample was passed to Virology. As part of the SCCRS HPV project this ID has been deprecated in favour of one ID for SCCRS, the "Lab No"
Cytology ID	This ID was previously generated when a sample was passed to Cytology. As part of the SCCRS HPV project this ID has been deprecated in favour of one ID for SCCRS, the "Lab No"

CCR / CCR ID	Cervical Cytology Request / Cervical Cytology Request ID As part of V3.0 this term will be replaced with CSR. This change is to reflect that SCCRS is no longer primarily Cytology.
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1.6 Version History

Version	Date	Reason for change	Author(s)
1a	01/12/2017	Initial Draft	John Dillett
1b	31/01/2018	Internal Feedback MN Extended introduction to include solution summary after meeting with NHS on 29/1/2018	John Dillett
1c	17/4/2018	Modified the interface to reflect changes to the project with the introduction of the Lab No.	John Dillett
1d	3/7/2018	Modified the interface to reflect changes to the project with using the CSRID (SCCRS number) to identify the sample	John Dillett

2 This Interface

NOTE: This document makes several assumptions regarding expected technologies used within the final solution. As such it should be regarded as indicative only. The interface will be formally reviewed and verified by all stakeholders once the capabilities of the middleware supplier has been determined and a full end to end process defined.

2.1 Summary

Currently screening tests in SCCRS are performed primarily through the Cytology service. Outcomes are determined through analysis of samples by assessment through microscopes. This is a labour-intensive process.

The SCCRS HR-HPV, as a primary test, project will introduce automated testing of Virology results into SCCRS. Virology testing will be performed by diagnostic analysers at various central LABS. A middleware application will communicate with the analysers, transform the results and send them into SCCRS via the SCCRS HR-HPV interface where they will be processed into the SCCRS application.

As part of the "SCCRS HR-HPV as the primary screening test" project, SCCRS will be extended to allow HR-HPV results sent from an analyser/middleware application to be received into SCCRS and processed automatically with minimum human intervention.

This document defines the interface that both systems must implement to achieve this.

2.2 Solution Overview

A new interface will be established based on the Health Level Seven(HL7) standards. Of the different HL7 variations HL7 2.4 standards over tcpip sockets will be used

- This standard is well supported across the healthcare industry
- It is already used in various systems within the NHS
- It allows re-use of existing interfaces already developed to minimise costs, risk and effort(BoSS).
- While there are emerging options such as HL7 FHIR these are relatively new. Using HL7 2 minimises the risk and cost for the NHS
- It is expected that the selected middleware provider will be able to deliver HL7 2.4 out the box

It is assumed that most exceptions will be handled in the SCCRS application. An exception report will be available in SCCRS to allow lab administrators to view any issues with results that cannot be processed into SCCRS

Interface High Level Requirements

The following list the overall aspects of the interface need to be supported by both the sender(middleware) and receiver(SCCRS)

- Will use HL7 2.4 standards over tcpip sockets
- Will be one-way (Middleware to SCCRS)
 - Results will be sent from the middleware to SCCRS on an ad-hoc basis(unsolicited)
 - No purchase order will be generated from SCCRS to the middleware
- Will handle sending of results and acknowledgement back to sending systems
 - Success/No Success receipt sent back to middleware
 - Reason for any Errors/Warnings sent to middleware
- Only final results will be delivered to SCCRS
- Result messages will provide at a minimum the following information required for SCCRS
 - Include a unique sample identifier. This will be the CSR ID (SCCRS Number).

- Contain the result of a test for high risk types of HPV with one of the following clear outcomes
 - Positive
 - Negative
 - Fail

The following defines additional aspects of the solution that needs to be supported by the sender(middleware)

- Be able to extract the Sample Identifier (CSR ID – with check digits) from a barcoded label present on the sample container.

Note: Depending on the final solution the sample container may have multiple barcodes.

2.3 Interface Delivery Responsibilities

The following roles and responsibilities are defined for this project.

2.4 Design

Component	Name (Role)
HR-HPV HL7 Message Service (SCCRS)	John Dillett
Delivery of agreed interface/content from the <<Middleware Supplier>>	<<Middleware Supplier>>

2.5 Design Approval

Component	Name (Role)
HR-HPV HL7 Message Service (SCCRS)	NHS Scotland
Delivery of agreed interface/content from the <<Middleware>>	NHS Scotland

2.6 Build

Component	Name (Role)
HR-HPV HL7 Message Service (SCCRS)	Atos Development Team
Delivery of agreed interface/content from the <<Middleware Supplier>>	<<Middleware Supplier>>

2.7 Test

Component	Name (Role)
HR-HPV HL7 Message Service (SCCRS)	Atos Development Team – Automated/Unit Testing
HR-HPV HL7 Message Service (SCCRS)	Atos Test Team – System testing
Delivery of agreed interface/content from the <<Middleware Supplier>>	<<Middleware Supplier>> – Development/Ops team
Overall end to end / UAT testing	NHS Scotland

2.8 Testing and Acceptance

Responsibility	Name (Role)
Provision of test harness	MLLP setup & message sending can be tested using an Atos in house HL7 sender application.
Provision of test data	The middleware supplier will sign off on this ICD and provide test messages generated by the analyser / middleware as a baseline for unit and system testing. This will be used for any subsequent testing of the interface.
Determining acceptance criteria	The delivery of messages into SCCRS is defined in the associated DFD documents for the project. These documents define the acceptance criteria for receipt of results. This document defines the overall content and protocols required between the different stakeholder involved in the interface.

3 System Identification

3.1 SCCRS – HL7 HR-HPV Service

The SCCRS HR-HPV service is a new component. It will be a windows service developed and running against .Net 4.x. This service will have the ability to receive, parse and process HL7 messages delivered over tcpip sockets into SCCRS. It will be configurable to meet the Minimal Low-Level Protocol (MLLP) as specified by the middleware software supplier. Messages received/processed will be audited in the SCCRS database.

A new exception report will be created in SCCR to allow administrators to monitor any issues with the interface.

3.2 Analyser/Middleware Supplier

The NHS will select a supplier to provide the analysers and middleware application for the project.

The middleware software will be responsible for communicating with the analysers and passing the results to SCCRS via the interface specification defined in this document.

At a minimum the following capabilities will be required from the middleware to interface to SCCRS

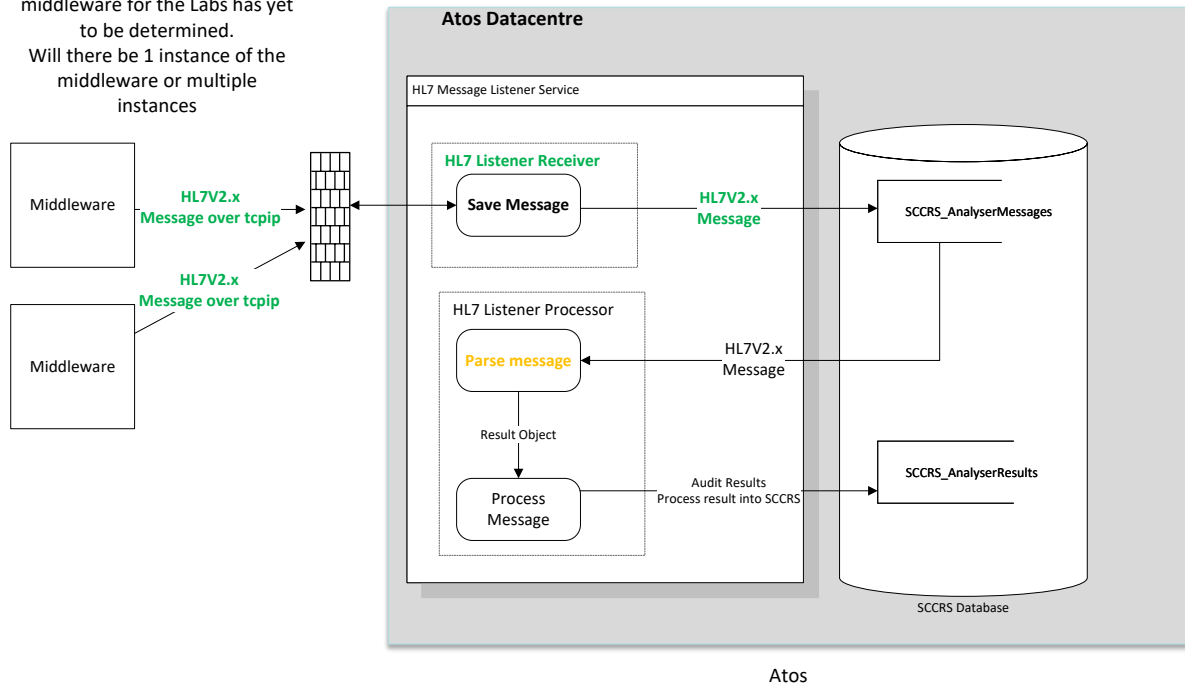
- A connector that will deliver final results to the SCCRS HPV Service
 - Send HL7 2.4 messages via tcpip sockets.
 - Communication using an agreed MLLP as per HL7 standards
- One-way sending of results from the middleware to SCCRS. Note: There will be no order request sent from SCCRS to the middleware.
- The analyser/middleware must be able provide at a minimum the following information required for SCCRS.
 - The HR-HPV result (Positive, Negative, Fail)
 - The Sample Identifier (SCCRS Number/ CSR ID)

Note: Depending on the final processes implemented by the Labs, there may be multiple barcodes on the container. This may have the SCCRS Number (CSRID with check digits) and the Lab No on two separate barcodes. A process (manual/automatic) will be required to ensure that the CSR ID is selected and delivered via the interface as the Sample Identifier.

- The middleware must have the capability to retry/resend message to the SCCRS listener when it is unavailable. If the SCCRS listener is unavailable for an extended (configurable) period of time, then the middleware will alert the administrator that an issue has occurred.
- The SCCRS listener will be configured to accept messages only during normal office hours. Out with these hours' messages will be rejected by the service with a NACK response. During this period the outstanding messages should not be highlight as an error. They will be resent when the system is available.

4 Interface Specification

The architecture of the middleware for the Labs has yet to be determined.
Will there be 1 instance of the middleware or multiple instances



The “SCCRS HR-HPV HL7 Service” is a windows service configured to listen on a defined IP address/port for supported HL7 message events. The protocol between the two systems(MLLP) will be agreed in advance but must be within the allowed criteria defined in this document.

The interface will be one-way from the middleware to SCCRS. No lab orders will be generated for the middleware prior to the results being received from the analyser.

Only the HL7 message content defined in this document will be supported. This is based on HL7 standard using the requirements defined for the SCCRS HR-HPV project as the basis for the requirements of the interface.

The SCCRS HL7 listener will accept and acknowledge that a message has been received and “saved” in SCCRS. The acknowledgement sent from the listener back to the middleware will follow HL7 2.4 standards for exchanging HL7 messages between systems.

Note: The SCCRS HL7 listener will not process the message prior to responding with an ACK. Another process (not defined in this document) will be responsible for processing the messages into SCCRS. Any errors encountered during the processing of the message will be recorded in an audit log in the SCCRS database and handled by SCCRS administration staff. An exception report will be available in SCCRS to make the exceptions visible to users in SCCRS.

4.1 Protocol

HL7 v2.4 commonly uses an MLLP protocol to deliver messages over tcpip sockets. This will be used for this interface.

The MLLP will be configurable. The specification for MLLP defined in the SCCRS listener will default to the Middleware Supplier specification.

All incoming messages received via the TCP socket will get a synchronous acknowledgement (real-time).

4.2 Transport Mechanism

Transport will be over tcpip.

4.3 Message Format

Version 2.4 of HL7 messages for the defined SCCRS HL7 Result specification only will be supported.

- The ACKS/NACKS should be generating using the original type response “Application” setting in the channel
- AE has an optional error message
- The incoming message to HL7 listener will always have AL in MHS-15
- During receipt of an HL7 transmission a basic check will be made that the format is acceptable and is an HL7 message of one of the supported types. If not supported, then an NACK will be generated and the message not saved for processing.
- Other errors/warnings will be handled in SCCRS via an online exception report.

HL7 Message Type(s) Supported

The following table defines the supported HL7 message type(s) used in the interface. The content for this type will be elaborated in additional detail below.

Validation Rules for Message Receipt

The following Rules will be checked during the receipt of the message.

If any of the following rules fail, the message is in error and a NACK sent back to the sending system

- The message follows the agreed MLLP
- The initial segment will be an MHS segment
- The value in MSH-9 is a valid message type
- Message Control ID will be present in the message header.
- Expected Message Format in MHS-12 is HL7 2.4
- MSH-15 - Accept Acknowledgement will be AL
- MSH-16 - Application Acknowledgement will be NE

HL7 message type	Use within SCCRS
ORU^R01	HL7 Message Type: Unsolicited transmission of an observation message HL7 Listener Message Type: Investigation Report This message type is used to accept incoming investigation reports into SCCRS.

HL7 Message Definition for ORU^R01

While HL7 defines segments/fields/components where information can be held it does not always match directly to the element(s) presented in these areas. This section defines the information relevant for consumption in SCCRS and the rules on how it will be processed into SCCRS.

The following represents a typical sample message that will be received from an HL7 result system. It consists of an MSH, ORC, OBR and one or more OBX entries for each result value.

At least one OBX with an identifier of IntHPVresult (Interpreted HR-HPV Result) will be required. The IntHPVresult OBX entry will have either a Positive, Negative or Fail value.

Sample Message

```
MSH|^~\&|IM|LABA|||20170708113839||ORU^R01||P|2.4|||AL|NE
ORC|RE|03721216|||^^^P||||
OBR|1|03721216|||^^^P||HM-Jack|^1^11^||||^^^P|||||
OBX|1|TX|IntHPVResult||Positive|||||20170708110541||TestAdmin||HM-Jack|20170708110541
OBX|2|TX|HPVType||HPV16|||||20170708110541||TestAdmin||HM-Jack|20170708110541
```

Sample Message Breakdown

```
MSH|^~\&|IM|FACILITYID|||MESSAGEID|ORU^R01|MESSAGECONTROLID|P|2.4|||AL|NE
ORC|RE|03721216|||^^^P||||
OBR|1|LabNo|||^^^P||HM-Jack|^1^11^||||^^^P|||||
OBX|1|TX|IntHPVResult||HPVRESULTVALUE|||||RESULTSTARTED||AUTHORISED||ANALYSERCODE|OBSERVATIONDATETIME
OBX|2|TX|HPVType||HPVTYPECODE|||||RESULTSTARTED||AUTHORISED||ANALYSERCODE|OBSERVATIONDATETIME
```

The sample message has been highlighted. All relevant data is now in bold with a short text value representing the name of the field as it will be saved in the SCCRS system. Certain fields may be repeated across different types however only the items in bold will be consumed by SCCRS.

(The short text is for descriptive purposes only. Field sizes and types are defined elsewhere in this document)

Validation Rules for Message Processing

The following Rules will be checked during the processing of the message.

If any of the following rules fail, the message is in error.

- Only one Result per message transmission (start/end frames of MLLP)
- Expected message type is ORU^R01
- It is expected that the message will always contain an MHS, ORC & OBR
- An OBX with an identifier (OBX 3.1) of "IntHPVResult" is mandatory.
 - Will have a value of either "Positive", "Negative" or "Fail"
- An OBX with an identifier (OBX 3.1) of "HPVType" is optional.
 - Will have a value indicating the HPVType
- The message will be processed into SCCRS as one result using the rules defined in the table below

Mapping of HL7 Standard to SCCRS HR-HPV Requirements

MSH Segment

Mandatory segment for message.

SCCRS Element	Description	Req	Max Size	HL7 V2 Field	SCCRS HR-HPV Requirements
Sending Application	This will be a unique ID for the sending middleware application	M	50	Sending Application	Need to be defined as a valid sending application in SCCRS
Message Date/Time	This represent the date time that the message was generated in the sending system	M		Message Date/Time	• If value is blank, then error • If value is not a valid date/time format, then an error will occur
LAB ID	This will be a unique ID for the sending SCCRS LAB	M	20	Sending Facility	Combined Virology/Cytology Labs are defined in SCCRS. This will represent the LAB that sent in the result. It will be maintained for audit purposes only.
Sender Message ID	This is the message identifier from the sending system	M	50	MESSAGE CONTROL ID	If available, the sending message identifier is a useful troubleshooting tool

OBR Segment

Mandatory segment for message.

SCCRS Element	Description	Req	Max Size	HL7 V2 Field	SCCRS HR-HPV Requirements
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CSR ID (SCCRS Number)	This will be the CSR ID – with check digits/SCCRS Number This is a unique ID for the Sample request in SCCRS. The ID is generated, as the sample is taken from the participant and applied to the sample container.	M	10	OBR Placer Order Number (OBR 2.1)	Middleware Supplier Description: "Specimen ID" - Middleware Supplier specification defines this element as optional but it is mandatory for SCCRS - If value is blank, then error - Will be a string - Has a maximum of 10 characters in length (including check digit)
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OBX Segment where Observation identifier(OBX 3.1) is "IntHPVResult"

Mandatory segment for message.

This OBX segment represents the interpreted HR-HPV result.

OBX segments are scanned for an Observation identifier (OBX 3.1) with a value of "IntHPVResult".

SCCRS Element	Description	Req	Max Size	HL7 V2 Field	SCCRS HR-HPV Requirements
Observation Identifier	Identifies a specific observation from other observations	M	20	Observation identifier (OBX-3.1)	Test Code
HR-HPV Result	HR-HPV Result This will be a string representing one of the allowable values	M	20	Observation value (OBX-5)	Middleware Supplier Description: "Test Result of" - If OBX not found, then message error - If value is blank, then error - If not one of the following values, then error Positive Negative Fail
Analyser Code	This will be a code that represents the analyser that performed the analysis.	M	50	Equipment Instance Identifier (OBX-18.1)	Middleware Supplier Description: "Test Instrument ID of" - If OBX not found, then message error - If value is blank, then error - If over max size then

					error
Authorised By	This represent the person who authorised the result	M	50	Responsible Observer (OBX 16.1)	Middleware Supplier Description: "Specimen Results Reviewed by" • If OBX not found, then message error • If value is blank, then error • If over max size then error
Analysers Observation Date/Time	This represent the date time that the analyser started the observation of the sample.	M		Analysis Date time (OBX 19.1)	Middleware Supplier Description: "Test Date Time Observation of" • If OBX not found, then message error • If value is blank, then error • If value is not a valid date/time format, then an error will occur

OBX Segment where Observation identifier (OBX 3.1) is "HPVType"

Optional segment for message.

This OBX segment represents any HPV Type found as part of the analysis of the sample. OBX segments are scanned for an Observation identifier (OBX 3.1) with a value of "HPVType".

SCCRS Element	Description	Req	Max Size	HL7 V2 Field	SCCRS HR-HPV Requirements
Observation Identifier	Identifies a specific observation from other observations	M	20	Observation identifier (OBX-3.1)	Test Code
HPV Type Code	HPV Type This will be a string representing one the type of HPV found as part of the analysis	M	50	Observation value (OBX-5)	Middleware Supplier Description: "Test Result of" • If OBX not found, then message error • If value is blank, then error • If over max size, then error

4.4 Invocation

The middleware software receives results from one or more analysers. These will be parsed/interpreted and queued up for sending to the SCCRS HR-HPV listener over the agreed protocol and MLLP.

The following steps will define the process for receipt of messages from a remote HL7client over tcpip sockets.

1. The SCCRS HL7 listener will listen on a pre-defined IP/PORT.
2. When an incoming connection request is detected a socket will be established and maintained between the listener and the client.
3. The open connection will be monitored for transmission of data.
4. Incoming data is processed and collated into a new message.
5. Once the end of frame is received the message is passed to the message parser.
6. The message is parsed to determine if it is a valid HL7 message.
7. Valid HL7 messages will be saved into a local data repository as a NEW incoming message. (Note: if an error occurs during this process then an Error ACK will be generated with a suitable error text)
8. ACK success message sent to client.
9. Go to step 3 (wait for new message)

NOTES:

Most of the message validation will occur during the processing of the message.

The middleware must have the capability to retry/resend message to the SCCRS listener when it is unavailable. If the SCCRS listener is unavailable for an extended (configurable) period of time then the middleware will alert the administrator that an issue has occurred.

The service will be configured to accept messages only during normal daily office hours(configurable). Out with these hours' messages will be rejected by the service as HL7 NACK. During this period the outstanding messages should not be highlight as an error for resolution.

If during parsing of the message (step 6)

- If not a valid message type (Basic HL7 message check) then a suitable NACK response message is returned.
- If message is itself an ACK then (e.g. ACK^A04) then do nothing.

In the normal course of events the service will keep the tcpip connection open and process messages as per the agreed MLLP. Several scenarios may cause the socket to terminate. Common scenarios are

- The listener service is stopped
- The client terminates the connection
- Network issues

4.5 Keep Alive

After a tcpip socket is established both the client and the server will attempt to keep the socket open unless specifically requested to close through application features.

4.6 Termination

Termination of the connection by the HL7 listener will be using standard start / stop events. A stop will terminate any open connections.

The listener will also monitor whether any active connections have been closed. This may be the client closing the connection or through network related issues. When this condition is detected then the internal server connection is closed and any open resources will be release.

4.7 Error Handling

This section describes how the HL7 listener delivers error messages for various scenarios that may occur that are specific to the interface define between the two systems.

The SCCRS HL7 listener complies with HL7 protocol for responding to message events with a suitable acknowledgement. Successful and Error / Reject support is defined for each interface.

The standard mode will be to acknowledge that the message has been received but not processed. The HL7 listener will only accept and acknowledge/respond to messages that have been received and saved in SCCRS. If not saved for any reason, then a NACK or possibly no response will be generated. In these scenarios, the middleware will attempt to resend the message at a later date.

The HL7 Listener only supports MHS-15 Accept Acknowledgment. MSH-16 is not supported. Any Acknowledgement will be for receipt of the message successfully only. The HL7 listener responds to a message event triggered by the remote system.

NOTE: Another process will be responsible for processing the message into SCCRS. Any issues encountered during this process are recorded in the SCCRS database and will be made available in an error report within the SCCRS web application.

4.7.1 Expectations on Middleware

This document concentrates on the capabilities of the HL7 interface. Exception management of the middleware is out of scope. There are however expectations on the middleware around exception handling for unexpected scenarios that may occur. These are required to allow the end to end interface to deliver a valid service for the interface to the SCCRS application.

- Any errors due to transmission will attempt to re-transmit at regular intervals. If after a defined amount of time or retries the transmission is still not possible then the system will alert a user for further investigation.
- Out of hours messages will be rejected by SCCRS. These should not be flagged as an alert
- Any un-expected error condition (e.g. invalid message) will be flagged immediately to a user for further investigation.

NOTE: A full list of known scenarios and the error messages that the middleware needs to support are defined below.

4.8 HL7 Listener Error Handling

There are several scenarios that may cause the HL7 Listener to generate an error. These are returned to the sending system in standard HL7 using the MSA segment.

Example Error Message

MSH|^~\&|TestReceivingApp|TestReceivingFac|||20151209144345||ACK|20151209144345|P|2.4||
MSA|AE|ID00000002|**Failed to parse incoming message**

Error Condition	ACK Type	Error Message Text
An internal unexpected error is	AE	"Unexpected Error encountered"

encountered. This is a catch all error that should not be encountered under normal circumstances. E.g. Network failure.		
SCCRS will have a period of downtime overnight where messages are not received. During this period, any attempt to send message will receive an error with the specified message.	AE	"System unavailable at this time"
During receipt of an HL7 message a check is made as to whether the message content meets the basic HL7 message requirements.	AE	"Failed to parse incoming message "

4.9 Security

Tcpip is controlled by point to point security. Networking and firewall configuration will be required to define the ports allowed between two tcpip end points.

4.10 Authentication

Tcpip is controlled by point to point security. Networking and firewall configuration will be required to define the ports allowed between two tcpip end points.

4.11 Authorisation

Tcpip is controlled by point to point security. Networking and firewall configuration will be required to define the ports allowed between two tcpip end points.

4.12 Auditing

All key events on the HL7 listener are audited to an event log. The log can be configured with various levels of detail. The default level will be minimal for normal operations.

Messages receive successfully are logged and audited in the database.

4.13 Encryption

No encryption is implemented in HL7.

4.14 Timing

Messages will be received as and when they are transmitted by the middleware in batches of up to 100.

4.15 Data Volumes and Throughput

Split across two labs there will an average of 1500 results a day with a maximum of 2500. These will be spread throughout the working lab day delivered in batches of around 100.

5 Test Approach

Several phases of testing will occur.

1. **Development Testing:** During development, an extensive suite of automated tests will allow all aspects of the interface to be tested. This will include end to end testing where test results will be sent using a test tcpip sending application to simulate the middleware. The test results will be processed through to completion. Each interim stage will be checked against expected outcomes in the database.
2. **System Testing:** As the interface is using standard HL7 protocols the test team will be able to emulate the middleware and send known test messages using a test sender utility. Messages manually sent will be processed to completion. The outcome in the database and how the messages are displayed will be validated by the team.
3. **User Acceptance Testing Pre-Release:** The user has requested advanced testing of the HL7 interface prior to the final delivery of the SCCRS release.
 - a. A test harness will be made available that allows testers to submit test message via a web browser. This will allow UAT testers to simulate the middleware for the pre-release system. The exact functionality available will be defined and communicated to the user as part of iteration planning.
 - b. A test environment will be made available to the user to allow them to perform an end to end test from the analyser through the middleware and into SCCRS database for the pre-release system. The exact functionality available will be defined and communicated to the user as part of iteration planning.
4. **User Acceptance Testing Final Release:** The final delivery of the SCCRS release will require full end to end testing of the messaging solution. A test environment will be made available to the user to allow them to perform an end to end test from the analyser through the middleware and into SCCRS database.

5.1 Testing Responsibility

Atos development and test staff will be responsible for defining the tests during development and system testing.

The User Acceptance test phases will require the involvement a combination of Atos development staff, Middleware Supplier, UAT testers and user representatives from the SCCRS screening centre.

Users will be responsible for defining the test cases during the two phases of UAT and running the test cases. Atos and Middleware Supplier will be available to provide support during this time.

5.2 Test Data

Atos development and test staff will be responsible for defining the tests data used during development and system testing. Test data will be generated based on the agreed interface formats and protocols and the samples generated by the middleware supplier. It will not have any live or sensitive data.

During the User Acceptance phases the users will be responsible for establishing the test data to meet their own test scenarios.

6 HL7 Message Definition

6.1 HL7 Listener Features Supported

Supported Features
The following Minimal Low-Level Protocol (MLLP) is configurable in the HL7 Listener per instance of the listener. This needs to be agreed on and defined as part of the listener setup. • Receiving Application • Receiving Facility • Listening Port number • Listening IP • Start Frame definition • Containing frame (header) • End Frame definition • Container Protocol definition
Individual Channels can be configured per sending application. This allows the AcknowledgementMode mode to be set per sending system. A default channel can be configured for unknown Sending Applications/Facilities • Sending Application • Sending Facility • AcknowledgementMode

6.2 HL7 Minimal Low-Level Protocol

A message transmission over tcpip for HL7 requires an agreed set of protocols to be agreed beforehand.

In order to provide a stream-oriented TCP/IP protocol, a Minimal Low-Level Protocol (MLLP) was chosen that is supported by the Middleware Supplier HL7 API.

This defines the message control characters.

The HL7 messages are enclosed by control characters in order to form a block.
The format is:

<sb>dddd<eb><cr>

- <sb> = Start Block character; ASCII 11dec, the vertical tab character
- dddd = the transmitted data; a variable number of bytes
- <eb> = End Block character; ASCII 28dec, it should not be confused with <etx> ASCII 3dec, or <etb> ASCII 23dec.
- <cr> = Carriage Return; ASCII 13dec.

The following HL7 format has been established to meet the supported values as per Middleware Supplier HL7 specification. Sample HL7 messages were used to verify and define the content of the message.

6.3 HL7 Message Format Definition

Version 2.4 of HL7 messages is supported for SCCRS

The HL7 2.4 specification defines several delimiters that are defined in the message header segment (MSH) at the start of the message.

The table below includes each of the delimiters in HL7 and provides details on its support in SCCRS.

Delimiter values

Delimiter	Expected Value	Usage	SCCRS support
Segment Terminator	<cr>	Terminates a segment record. This value cannot be changed by implementers.	<cr>, <lf> and <cr><lf>
Field Separator		Separates two adjacent data fields within a segment. It also separates the segment ID from the first data field in each segment.	
Component Separator	^	Separates adjacent components of data fields where allowed.	
Repetition Separator	~	Separates multiple occurrences of a field where allowed.	
Escape Character	\	Escape character for use with any field represented by an ST, TX or FT data type, or for use with the data (fourth) component of the ED data type. If no escape characters are used in a message, this character may be omitted. However, it must be present if subcomponents are used in the message. Best practice is to always include this character.	
Sub component Separator	&	Separates adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted. Best practice is to always include this character.	

Channel Configuration

A separate channel is configured for each application that wishes to send HL7 messages to the HL7 listener. Each channel has the following configuration items that are relevant for a system developer of such a sending application: -

Channel Details	SendingApplication ("Application Name") SendingFacility ("Application Instance .e.g. SCCRSLab") The combination of Sending Application and Sending Facility must be unique.
HL7 Ack Mode	HL7AckMode Commit Application Never

Basic HL7 Message Validation

Each HL7 message needs to have at a minimum the following definition for it to be valid. The message will respond with a reject if the check is not correct.

- MSH-1 – Header segment present
- MSH-2 – Encoding Characters
- MSH-3 – Sending Application
- MSH-9 – Message Type
- MSH-10 – Message Control ID
- MSH-11 – Processing ID
- MSH-12 – Version ID

Example

```
MSH|^~\&|SendingApp| |||||ORU^R01|ID20151204130632|P|2.4|
```

Acknowledgement message

For all situations except the QRY response we will respond with an ACK acknowledgement message to signify success.

Acknowledgment messages contain the following HL7 interface segments:

NOTE: Single character responses are not supported at this time.

MSH – Message header segment

MSA – Message acknowledgment segment

The MSH segment in the response is constructed based on the following :-

- MSH-7-date/time of message and MSH-10-message controlID refer to the response message; they are not echoes of the fields in the initial message.
- MSH-5-receiving application, MSH6-receiving facility and MSH-11 processing ID contain codes that are copied from MSH-3-sending application, MSH-4 sending facility and MSH-11-processing ID in the initiating message.
- MSH-9-MessageType TriggerEventStandard protocol is to respond with MessageType “ACK” and the TriggerEvent from the originating message. So, a message being received with MSH-9 of ADT^A04 will be acknowledged with ACK^A04

In all the responses described above, the following values are put into the MSA segment

Field	Notes
<i>MSA-1-acknowledgment code</i>	Mandatory As described in the “AckMode” table below.
<i>MSA-2-message control ID</i>	Mandatory MSH-10-message control ID from MSH segment of incoming message.
<i>MSA-3-Text Message</i>	Optional segment

	Contains text describing the error for an error condition.
<i>MSA-4-expected sequence number</i>	N/A
ERR segment fields	N/A

Note: HL7 error segments are not supported at this time.

The receiving application then passes the response message back to the responding system.

Response acknowledgement codes

HL7 acknowledgment messages may contain one of three status codes from the receiving system - Accept, Error or Reject.

NOTE: Both Error and Reject types should be regarded as fatal in the sending system.

Each channel has an element "Ack Mode" that defines how the message is acknowledged.

Valid values for this are defined in the table below.

The following are valid acknowledgement message types

- The message was received successfully, generating the functional response message with a success acknowledgement code.
- Send an error response, providing error information in functional segments to be included in the response message with a value and error acknowledgement code
- fail to process (reject) the message for reasons unrelated to its content or format (system down, internal error, etc.). For most such problems it is likely that the responding system will be able to accept the same message at a later time. The sending application is responsible to decide on-specific basis whether the message should be automatically sent again. The response message contains a value with a reject acknowledgement code.

ACK Mode

Value	Details
Never	No Acknowledge message is generated.
Application	Original Mode: If this has a value of "Application" then values are AA – Application Accept AE – Application Error AR – Application Reject
Commit (DEFAULT)	Enhanced Mode: If this has a value of "Commit" then values are CA — Accept acknowledgment: Commit Accept CE — Accept acknowledgment: Commit Error CR — Accept acknowledgment: Commit Reject

Sample Success Message

MSH|^~\&|ReceivingApp|ReceivingFac|ReqApp|ReqFac|20151204130632||ACK^R01|20151204130632|P|2.4|
MSA|AA|**MessageControl**|Message received successfully

Sample Error Messages

MSH|^~\&|TestReceivingApp|TestReceivingFac|DummyTestApp|DummyTestFac|20151204132526||ACK^A04|20151204132526|P|2.4|
MSA|AR|ID00000002|File delivery directory does not exist

MSH|^~\&|TestReceivingApp|TestReceivingFac|||20151209144345||ACK|20151209144345|P|2.1||
MSA|AE|ID00000002|Failed to parse incoming message