

Oncospace, Inc.

Oncospace System

DICOM Conformance Statement

Copyright © 2022 Oncospace Incorporated. All rights reserved.

The Oncospace™ software, documentation and all content including text, graphics, interfaces, trademarks, logos, artwork, computer code, design, structure, selection, co-ordination, expression and arrangement is protected by copyright, patent and trade mark laws, and various other intellectual property rights and unfair competition laws.

Oncospace Incorporated provides this guide without warranty of any kind, either implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

The Oncospace™ software, documentation, and content are provided under a license agreement ('End User Agreement') containing restrictions on their use, disclosure, reproduction, transmission, and distribution. Reverse engineering of the software is strictly prohibited.

E-mail: support@oncospac.com

Web site: www.oncospac.com



1 CONFORMANCE STATEMENT OVERVIEW

The *Oncospace System* provides radiation therapy treatment planning guidance and review as a service over the internet. The *Oncospace Edge Agent* (OEA) is the on-premises component of the *Oncospace System* that receives DICOM CT Images and DICOM RT Instances from a *Treatment Planning System* (TPS). It then de-identifies the images as described in Section 8.4, and transmits them to the *Dedicated Cloud Services* that have been provisioned for the *Oncospace Customer*. The output from the *Oncospace System* is retrieved by making an API call from the *Treatment Planning System* to the *Oncospace Edge Agent*, which in turn obtains that data from the *Oncospace Distributed Cloud Services*.

The *Oncospace Edge Agent* provides a DICOM Storage Service SCP only. The network services supported by the *Oncospace Edge Agent* are as follows:

Table 1: Network Services

DICOM SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
CT Image Storage	No	Yes
RT Structure Set Storage	No	Yes
RT Plan Storage	No	Yes
RT Dose Storage	No	Yes

2 TABLE OF CONTENTS

1	CONFORMANCE STATEMENT OVERVIEW.....	2
2	TABLE OF CONTENTS.....	3
3	INTRODUCTION.....	5
3.1	Revision History.....	5
3.2	Audience.....	5
3.3	Remarks	5
3.4	Terms and Definitions.....	7
3.5	Basics of DICOM Communication	8
3.6	Abbreviations	9
3.7	References	10
3.8	Privacy Statement.....	10
4	NETWORKING.....	12
4.1	Implementation Model	12
4.1.1	Application Data Flow	12
4.1.2	Functional Definition of AE's	13
4.1.3	Sequencing of Real-World Activities	13
4.2	AE Specifications.....	14
4.2.1	Local DICOM Storage SCP.....	14
4.3	Network Interfaces.....	18
4.3.1	Physical Network Interface.....	18
4.3.2	Additional Protocols	18
4.3.3	IPv4 and IPv6 Support.....	19
4.4	Configuration	19
4.4.1	AE Title/Presentation Address Mapping.....	19
4.4.2	Parameters	19
5	MEDIA INTERCHANGE	20
6	TRANSFORMATION OF DICOM TO CDA	20
7	SUPPORT OF CHARACTER SETS	20

8	SECURITY.....	21
8.1	Security Profiles.....	21
8.2	Association Level Security.....	21
8.3	Application Level Security.....	21
8.4	Basic Application Level Confidentiality Profile	21
9	ANNEXES.....	24
9.1	IOD Contents.....	24
9.1.1	Created SOP Instances	24
9.1.2	Usage of Attributes from Received IODs.....	24
9.1.3	Attribute Mapping.....	24
9.1.4	Coerced/Modified Fields	24
9.2	Data Dictionary of Private Attributes	24
9.3	Coded Terminology and Templates.....	24
9.4	Grayscale Image Consistency	25
9.5	Standard Extended/Specialized/Private SOP Classes	25
9.6	Private Transfer Syntaxes	25

3 INTRODUCTION

3.1 Revision History

Revision	Date	Author	Change
1	2020-08-04	Oncospace Engineering	Initial version (first product release).
2	2022-06-02	Oncospace Engineering	Updates for 2022 product release; Updated logo; Change terminology to “dedicated Cloud services”; Added referenced to product About Box in Section 3.8; Added description of cloud processing sequencing in Section 4.2.1.4; Added note on data encryption in Section 8.4; Minor changes to retained descriptors in Section 8.4.

3.2 Audience

The reader of this document is concerned with software design and/or system integration issues. It is assumed that the reader of this document is familiar with the DICOM Standards and with the terminology and concepts that are used in those Standards.

If readers are unfamiliar with DICOM terminology, they should read the DICOM Standard before reading this Conformance Statement document.

3.3 Remarks

The use of this DICOM Conformance Statement, in conjunction with the DICOM v3.X Standards, is intended to facilitate communication with the Oncospace System. However, by itself, it is not sufficient to ensure that inter-operation will be successful. The user (or user’s agent) needs to proceed with caution and address at least four issues:

- Integration:** The integration of any device into an overall system of interconnected devices goes beyond the scope of standards (DICOM v3.0), and of this DICOM Conformance Statement when interoperability with non-Oncospace equipment is desired. The responsibility to analyze the application’s requirements and to design a solution that integrates the Oncospace System with non–Oncospace systems is the user’s

responsibility and should not be underestimated. The user is strongly advised to ensure that such an integration analysis is correctly performed.

- **Validation:** Testing the complete range of possible interactions between the Oncospace System and non–Oncospace devices, before the connection is declared operational, should not be overlooked. Therefore, the user should ensure that any non–Oncospace provider accepts full responsibility for all validation required for their connection with the Oncospace System. This includes the accuracy of the image data once it has crossed the interface between the *Oncospace System* and the non–Oncospace device and the stability of the image for the intended applications.

Such a validation is required before any clinical use (treatment planning and/or delivery) is performed. It applies when images acquired on non-Oncospace imaging equipment are processed/displayed on the Oncospace System, and when images are exported from the Oncospace System to a non-Oncospace device.

- **Future Evolution:** Oncospace Incorporated understands that the DICOM Standard will evolve to meet the user’s growing requirements. Oncospace Incorporated actively follows the development of the DICOM 3.0 Standard. DICOM 3.0 will incorporate new features and technologies and Oncospace Incorporated may follow the evolution of the Standard. Evolution of the Standard may require changes to the Oncospace System. In addition, Oncospace Incorporated reserves the right to discontinue or make changes to the support of communications features (on its products) reflected on by this DICOM Conformance Statement. The user should ensure that any non–Oncospace provider, which connects with the Oncospace System, also plans for future evolution of the DICOM Standard. Failure to do so will likely result in the loss of function and/or connectivity as the DICOM Standard changes and the Oncospace System is enhanced to support these changes.
- **Interaction:** It is the sole responsibility of the non–Oncospace provider to ensure that communication with the interfaced equipment does not cause degradation of the Oncospace System performance and/or function.

3.4 Terms and Definitions

Abstract Syntax	The information agreed to be exchanged between applications, generally equivalent to a Service/Object Pair (SOP) Class. Examples: Verification SOP Class, Modality Worklist Information Model Find SOP Class, Computed Radiography Image Storage SOP Class.
Application Entity (AE)	An end point of a DICOM information exchange, including the DICOM network or media interface software, i.e., the software that sends or receives DICOM information objects or messages. A single device may have multiple Application Entities.
Application Entity Title (AET)	The externally known name of an <i>Application Entity</i> , used to identify a DICOM application to other DICOM applications on the network.
Application Context	The specification of the type of communication used between <i>Application Entities</i> . Example: DICOM network protocol.
Association	A network communication channel set up between <i>Application Entities</i> .
Attribute	A unit of information in an object definition; a data element identified by a <i>tag</i> . The information may be a complex data structure (Sequence), itself composed of lower level data elements. Examples: Patient ID (0010,0020), Accession Number (0008,0050), Photometric Interpretation (0028,0004), Procedure Code Sequence (0008,1032).
Information Object Definition (IOD)	The specified set of <i>Attributes</i> that comprise a type of data object; does not represent a specific instance of the data object, but rather a class of similar data objects that have the same properties. The <i>Attributes</i> may be specified as Mandatory (Type 1), Required but possibly unknown (Type 2), or Optional (Type 3), and there may be conditions associated with the use of an Attribute (Types 1C and 2C). Examples: MR Image IOD, CT Image IOD, Print Job IOD.
Module	A set of <i>Attributes</i> within an <i>Information Object Definition</i> that are logically related to each other. Example: Patient Module includes Patient Name, Patient ID, Patient Birth Date, and Patient Sex.
Negotiation	First phase of <i>Association</i> establishment that allows <i>Application Entities</i> to agree on the types of data to be exchanged and how that data will be encoded.
Presentation Context	The set of DICOM network services used over an <i>Association</i> , as negotiated between <i>Application Entities</i> ; includes <i>Abstract Syntaxes</i> and <i>Transfer Syntaxes</i> .
Protocol Data Unit (PDU)	A packet (piece) of a DICOM message sent across the network. Devices must specify the maximum size packet they can receive for DICOM messages.
Security Profile	A set of mechanisms, such as encryption, user authentication, or digital signatures, used by an <i>Application Entity</i> to ensure confidentiality, integrity, and/or availability of exchanged DICOM data.
Service Class Provider (SCP)	Role of an <i>Application Entity</i> that provides a DICOM network service; typically, a server that performs operations requested by another <i>Application Entity</i> (<i>Service Class User</i>). Examples: Picture Archiving and Communication System (image storage SCP, and image query/retrieve SCP), Radiology Information System (modality worklist SCP).

Service Class User (SCU)	Role of an <i>Application Entity</i> that uses a DICOM network service; typically, a client. Examples: imaging modality (image storage SCU, and modality worklist SCU), imaging workstation (image query/retrieve SCU).
Service/Object Pair Class (SOP Class)	The specification of the network or media transfer (service) of a particular type of data (object); the fundamental unit of DICOM interoperability specification. Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.
Service/Object Pair Instance (SOP Instance)	An information object; a specific occurrence of information exchanged in a <i>SOP Class</i> . Examples: a specific x-ray image.
Tag	A 32-bit identifier for a data element, represented as a pair of four-digit hexadecimal numbers, the "group" and the "element". If the "group" number is odd, the tag is for a private (manufacturer-specific) data element. Examples: (0010,0020) [Patient ID], (07FE,0010) [Pixel Data], (0019,0210) [private data element].
Transfer Syntax	The encoding used for exchange of DICOM information objects and messages. Examples: <i>JPEG</i> compressed (images), little endian explicit value representation.
Unique Identifier (UID)	A globally unique "dotted decimal" string that identifies a specific object or a class of objects; an ISO-8824 Object Identifier. Examples: Study Instance UID, SOP Class UID, SOP Instance UID.
Value Representation (VR)	The format type of an individual DICOM data element, such as text, an integer, a person's name, or a code. DICOM information objects can be transmitted with either explicit identification of the type of each data element (Explicit VR), or without explicit identification (Implicit VR); with Implicit VR, the receiving application must use a DICOM data dictionary to look up the format of each data element.

3.5 Basics of DICOM Communication

This section describes terminology used in this Conformance Statement for the non-specialist. The key terms used in the Conformance Statement are highlighted in *italics* below. This section is not a substitute for training about DICOM, and it makes many simplifications about the meanings of DICOM terms.

Two *Application Entities* (devices) that want to communicate with each other over a network using DICOM protocol must first agree on several things during an initial network "handshake". One of the two devices must initiate an *Association* (a connection to the other device), and ask if specific services, information, and encoding can be supported by the other device (*Negotiation*).

DICOM specifies several network services and types of information objects, each of which is called an *Abstract Syntax* for the Negotiation. DICOM also specifies a variety of methods for encoding data, denoted *Transfer Syntaxes*. The Negotiation allows the initiating Application Entity to propose combinations of Abstract Syntax and Transfer Syntax to be used on the Association; these combinations are called *Presentation*

Contexts. The receiving Application Entity accepts the Presentation Contexts it supports.

For each Presentation Context, the Association Negotiation also allows the devices to agree on *Roles* - which one is the *Service Class User* (SCU - client) and which is the *Service Class Provider* (SCP - server). Normally the device initiating the connection is the SCU, i.e., the client system calls the server, but not always.

The Association Negotiation finally enables exchange of maximum network packet (*PDU*) size, security information, and network service options (called *Extended Negotiation* information).

The Application Entities, having negotiated the Association parameters, may now commence exchanging data. Common data exchanges include queries for worklists and lists of stored images, transfer of image objects and analyses (structured reports) and sending images to film printers. Each exchangeable unit of data is formatted by the sender in accordance with the appropriate *Information Object Definition* and sent using the negotiated Transfer Syntax. There is a Default Transfer Syntax that all systems must accept, but it may not be the most efficient for some use cases. Each transfer is explicitly acknowledged by the receiver with a *Response Status* indicating success, failure, or that query or retrieve operations are still in process.

Two Application Entities may also communicate with each other by exchanging media (such as a CD-R). Since there is no Association Negotiation possible, they both use a *Media Application Profile* that specifies "pre-negotiated" exchange media format, Abstract Syntax, and Transfer Syntax.

3.6 Abbreviations

AE	Application Entity
AET	Application Entity Title
API	Application Programming Interface
CT	Computed Tomography
DHCP	Dynamic Host Configuration Protocol
DICOM	Digital Imaging and Communications in Medicine
DNS	Domain Name System
HIS	Hospital Information System
HL7	Health Level 7 Standard
IHE	Integrating the Healthcare Enterprise
IOD	Information Object Definition

IPv4	Internet Protocol version 4
IPv6	Internet Protocol version 6
ISO	International Organization for Standards
O	Optional (Key Attribute)
OSI	Open Systems Interconnection
OEA	Oncospace Edge Agent
OWA	Oncospace Web Application
PACS	Picture Archiving and Communication System
PDU	Protocol Data Unit
R	Required (Key Attribute)
RDN	Relative Distinguished Name (LDAP)
RT	Radiotherapy
SCP	Service Class Provider
SCU	Service Class User
SOP	Service-Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
TPS	Treatment Planning System
U	Unique (Key Attribute)
UL	Upper Layer
VR	Value Representation

3.7 References

- NEMA PS3 Digital Imaging and Communications in Medicine (DICOM) Standard, available free at <http://medical.nema.org/>.

3.8 Privacy Statement

Oncospace Incorporated is committed to providing medical equipment that helps customers to be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The following specific features and design measures have been incorporated into the Oncospace® System to facilitate this:

The point of connection between the facility and the customer-supplied hardware running the *Oncospace Edge Agent* is inside the organization's firewall device, typically



Type: DICOM Conformance Statement

Revision: 2 June 2022 (Rev 2)

configured to allow only specific, controlled forms of network traffic (for example, DICOM import).

The workstation or portable device running the *Oncospace Web Application* can be protected by Windows® system, an Android password, or an Apple iOS® password, and the *Oncospace Web Application* itself is protected by user-specific identifies managed using the Customer's Azure Active Directory.

User account timeout is provided on the *Oncospace Web Application*.

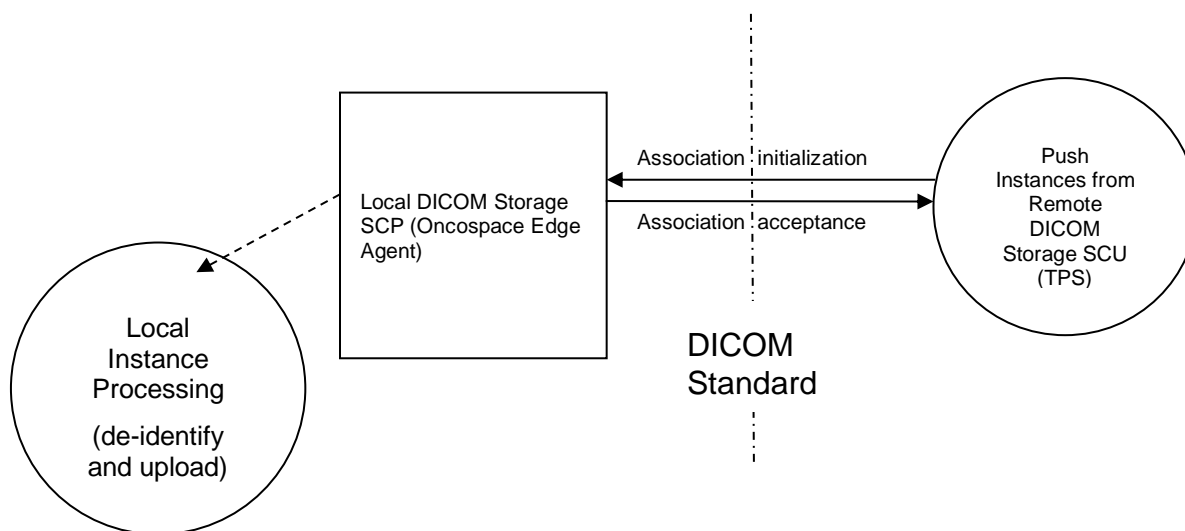
A detailed Oncospace Product Privacy Statement is available from the "About" box of the Oncospace Web Application.

4 NETWORKING

4.1 Implementation Model

4.1.1 Application Data Flow

The following diagram depicts the Application Entities (AE) and their relationship into the Real-World Activities.



The Local Image Processing is initiated when the *Oncospace Edge Agent* is launched. The Local DICOM Storage SCP (for incoming CT images and RT Instances) is launched at application startup with the configured AE Title and listening port.

A Remote DICOM Storage SCU initiates a push of DICOM instances to the Local DICOM Storage SCP on the *Oncospace Edge Agent*. Each instance accepted is passed to Local Instance Processing, to be processed asynchronously – de-identified then uploaded to the *Dedicated Cloud Services* for the Customer – and when this processing has started a success status is returned for the store operation.

When all store operations have been received and queued for processing, the Remote DICOM Storage SCU requests that the associated be closed. At this point, Local Instance Processing waits for processing (upload) to finish for any remaining instances, then closes the association after returning a successful response.

Instances that are accepted by the Local DICOM Storage SCP are stored temporarily in the *Oncospace Edge Agent* live memory only, until uploaded.

4.1.2 Functional Definition of AE's

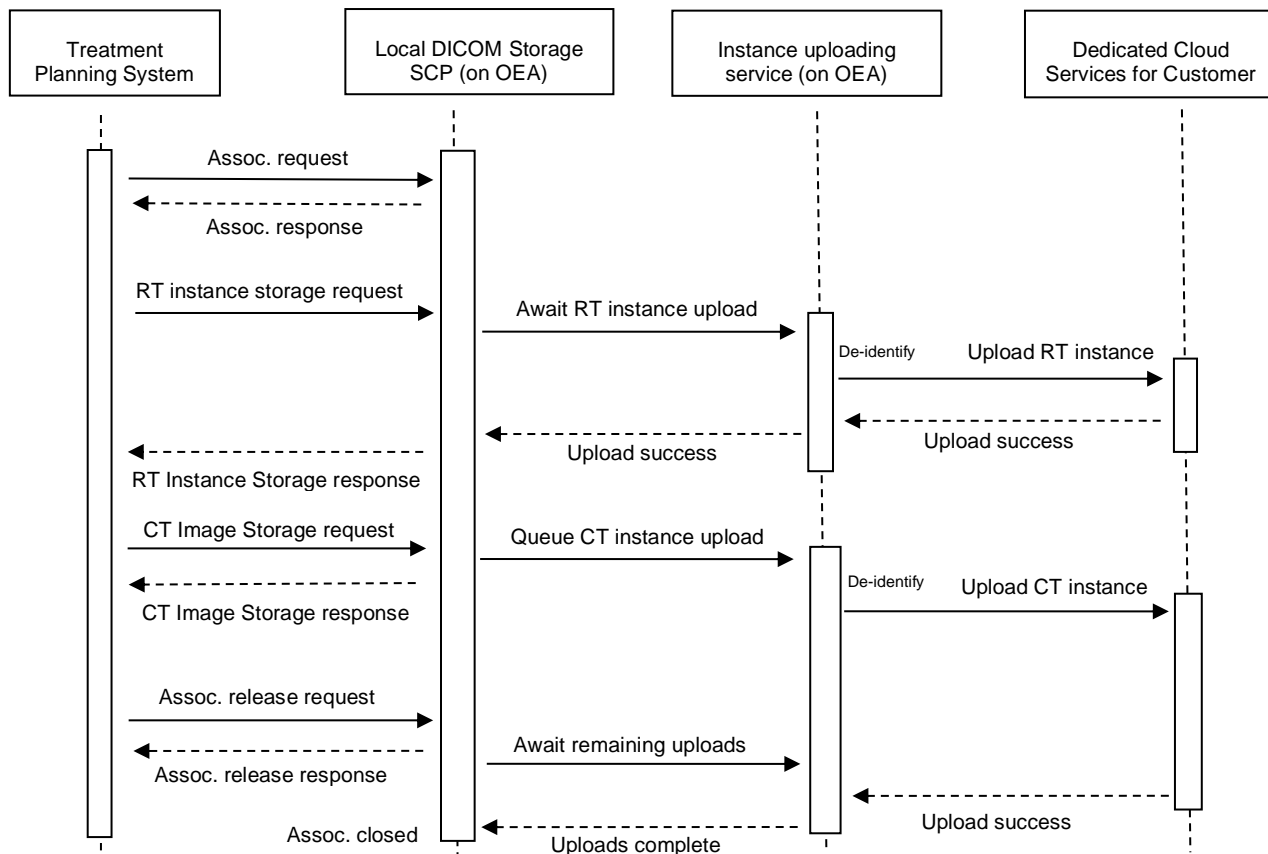
4.1.2.1 Functional Definition of the Local DICOM Storage SCP

The *Oncospace Edge Agent* implements a Service Class Provider (SCP) for the Storage Service Class. It listens on a specific TCP/IP port for incoming association requests from a Storage Service Class User (SCU) and can receive and process CT images and certain Radiotherapy IOD instances. The Storage SCP application also supports the Verification Service Class as an SCP. It will reject all other proposed storage service classes.

4.1.3 Sequencing of Real-World Activities

The real-world activity *Receive Instances from a Remote DICOM Storage SCU* is triggered when an image is sent from the modality or another DICOM entity:

- The Local DICOM Storage SCP AE responds to a DICOM association initiation from the *Treatment Planning System* and selects a set of matching Presentation Contexts (Abstract Syntax and Transfer Syntax). It accepts the association and waits for C-STORE requests.
- Upon receiving each C-STORE request:
 - For an **RT Instance** (RT SS, RT Plan, or RT Dose) from the *Treatment Planning System*, the Local DICOM Storage SCP **sends** the instance in live memory to an instance uploading service running within the *Oncospace Edge Agent*, **waits for the result**, and sends a C-STORE response back to the calling SCU.
 - Upon receiving each C-STORE request for an **CT Image** from the *Treatment Planning System*, the Local DICOM Storage SCP **queues** the instance in live memory to an instance uploading service running within the *Oncospace Edge Agent*, **does not wait for the result**, and sends a C-STORE response back to the calling SCU.
- Upon completion of all instance transfers, the Treatment Planning System sends an association release request to the Local DICOM Storage SCP.
- The Local DICOM Storage SCP immediately responds to the association release request.
- The Local DICOM Storage SCP then awaits upload of any remaining CT Image instances being processed by the instance uploading service and closes the association.



4.2 AE Specifications

4.2.1 Local DICOM Storage SCP

4.2.1.1 SOP Classes

This Application Entity provides Standard Conformance to the following DICOM SOP Classes:

SOP Classes	SOP Class UID	SCU	SCP
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	No	Yes
RT Structure Set Storage	1.2.840.10008.5.1.4.1.1.481.3	No	Yes
RT Plan Storage	1.2.840.10008.5.1.4.1.1.481.5	No	Yes
RT Dose Storage	1.2.840.10008.5.1.4.1.1.481.2	No	Yes

4.2.1.2 Association Policies

4.2.1.2.1 General

The DICOM standard application context name for DICOM 3.0 is always proposed:

DICOM Application Context for Local DICOM Storage SCP	
Application Context Name	1.2.840.10008.3.1.1.1

The maximum PDU length is 16384 bytes.

4.2.1.2.2 Number of Associations

The Local DICOM Storage SCP does not propose associations. The number of simultaneous associations that the Local DICOM Storage SCP will accept is limited only by the underlying TCP/IP implementation.

Number of Associations as an association acceptor for Local DICOM Storage SCP	
Maximum number of simultaneous associations	No application limit. Limit may be imposed by the O/S.

4.2.1.2.3 Asynchronous Nature

Asynchronous mode is not supported. All operations are performed synchronously.

Asynchronous Nature as an association acceptor for Local DICOM Storage SCP	
Maximum number of outstanding asynchronous transactions	1

4.2.1.2.4 Implementation Identifying Information

Number of Associations as an association initiator for Local DICOM Storage SCP	
Implementation Class UID	1.3.6.1.4.1.30071.8
Implementation Version Name	fo-dicom 5.x.x

4.2.1.3 Association Initiation Policy

The Local DICOM Storage SCP does not initiate associations.

4.2.1.4 Association Acceptance Policy

The Local DICOM Storage SCP accepts an association when it receives a valid association request, with at least one matching presentation context.

4.2.1.4.1 Real-world Activity – ‘Receive Instances from a Remote DICOM Storage SCU’

4.2.1.4.1.1 Description and Sequencing of Activities

The Real-World Activity is associated with a C-STORE SCP operation (Local DICOM Storage SCP Application Entity) and is triggered by a Push (C-Store) of images from the Remote DICOM Storage SCU (typically a *Treatment Planning System*). This results in the de-identification of the received instances on the *Oncospace Edge Agent* and their upload to the *Dedicated Cloud Services* for the Customer.

Cloud processing of uploaded data is triggered by the arrival of an RT Structure Set. When this occurs, the referenced CT Image instances are located, and if they are not already present then processing waits for their arrival (this can occur if images are sent concurrently with the RT Structure Set, for example, in a separate association). Any RT Plan and RT Dose instances transmitted in the same association as the RT Structure Set are also processed.

See Section 4.1.3 for more detailed sequencing of DICOM operations.

4.2.1.4.1.2 Accepted Presentation Contexts

The Local DICOM Storage SCP accepts the Presentation Contexts shown in the following table:

Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
RT Structure Set Storage	1.2.840.10008.5.1.4.1.1.481.3				
RT Plan Storage	1.2.840.10008.5.1.4.1.1.481.5	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
RT Dose Storage	1.2.840.10008.5.1.4.1.1.481.2				

When presented with multiple transfer syntaxes within one requested Presentation Context, the Local DICOM Storage SCP accepts the first transfer syntax according to the order of the table above.

4.2.1.4.1.3 SOP-Specific Conformance for All Storage SOP Classes

The following table lists the possible values for the Status (0000, 0900) attribute of the C-STORE response:

Service Status	Further Meaning	Error Code	Reason
Success	Success	0000	The DICOM instance was successfully received and stored in the local system, ready for processing.
Failure	SOP Class Not Supported	0122	The supplied SOP Instance was not one of the SOP classes negotiated in the association.
Error	Data Set does not match SOP class	A900	The SOP Class UID or SOP Instance UID in the C-STORE-RQ does not match the corresponding UID in the received dataset. The DICOM instance was not stored.
Failure	Cannot understand	C000	The received DICOM instance did not include a SOP Class UID or SOP Instance UID. The DICOM instance was not stored.
Error	Processing Failure	0110	De-identification failed or upload failed (due to cloud connectivity or authentication issues)

4.2.1.4.2 Real-world Activity – ‘Echo Operation’

4.2.1.4.2.1 Description and Sequencing of Activities

The Real-World Activity ‘Echo Operation’ is associated with a C-STORE SCP operation (Local DICOM Storage SCP Application Entity) and is triggered by a Verify (C-Echo) request from the Remote DICOM Storage SCU (typically a *Treatment Planning System*).

4.2.1.4.2.2 Accepted Presentation Contexts

The Local DICOM Storage SCP accepts the Presentation Contexts shown in the following table:

Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Verification SOP Class	1.2.840.10008.1.1	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
		Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

When presented with multiple transfer syntaxes within one requested Presentation Context, the Local DICOM Storage SCP accepts the first transfer syntax according to the order of the table above.

4.2.1.4.2.3 SOP-Specific Conformance for Verify SOP Class

The AE provides standard conformance to the Verification SOP Class as a SCP.

4.3 Network Interfaces

4.3.1 Physical Network Interface

Oncospace Edge Agent supports a single network interface. One of the following physical network interfaces will be available depending on installed hardware options. Use of at least 1000BaseT is recommended.

Supported Physical Network Interfaces
Ethernet 10GBaseT
Ethernet 1000BaseT
Ethernet 100BaseT

4.3.2 Additional Protocols

None.

4.3.3 IPv4 and IPv6 Support

This product only supports IPv4 connections.

4.4 Configuration

4.4.1 AE Title/Presentation Address Mapping

4.4.1.1 Local AE Titles

The Local DICOM Storage SCP uses an AE Title and TCP/IP Port configured via settings obtained from the *Dedicated Cloud Services* for that Customer. Default values are:

Application Entity	Default AE Title	Default TCP/IP Port
Local DICOM SCP	ONCOSPACE	11112

4.4.1.2 Remote AE Title/Presentation Address Mapping

4.4.1.2.1 Remote Input Devices

The Local DICOM Storage SCP accepts incoming associations from all calling AE Titles and hosts on the clinic's local network.

4.4.1.2.2 Remote Output Devices

Not applicable.

4.4.2 Parameters

Certain parameters can be configured by Oncospace staff at the Customer's request, via settings in the *Dedicated Cloud Services* for the Customer. The table below only shows those configuration parameters relevant to DICOM communication.

Parameter	Configurable (Yes/No)	Default Value
General Parameters		
Max PDU Receive Size	No	16384 bytes

Max PDU Send Size	No	16384 bytes
Local DICOM SCP		
Listening port	Yes	11112
AE Title	Yes	ONCOSPAC
Maximum Time for Study	No	Infinite

5 MEDIA INTERCHANGE

There is no media interchange application profile support.

6 TRANSFORMATION OF DICOM TO CDA

There is no support for SR or CDA documents.

7 SUPPORT OF CHARACTER SETS

In addition to the default character set, *Oncospace Edge Agent* supports the following character sets:

- ISO_IR 100 (ISO 8859-1:1987 Latin Alphabet No. 1 supplementary set)

8 SECURITY

8.1 Security Profiles

The *Oncospace Edge Agent* does not support DICOM security profiles related to the on-premises communication between the *Treatment Planning System* and the *Oncospace Edge Agent*. Communication between the *Oncospace Edge Agent* and the *Dedicated Cloud Services* for the Customer occurs using non-DICOM protocols (secure RESTful storage provided by the Azure Cloud platform and a secure API call provided by an Azure Function).

It is assumed that the *Oncospace Edge Agent* is used within a secured environment. It is also assumed that a secured environment includes at a minimum:

- a) Firewall or router protections to ensure that only approved external hosts have network access.
- b) Firewall or router protections to ensure that the *Oncospace Edge Agent* only has network access to approved external hosts and services.
- c) Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels (e.g. such as a Virtual Private Network (VPN)).

Other network security procedures such as automated intrusion detection may be appropriate in some environments. Additional security features may be established by the local security policy and are beyond the scope of this conformance statement.

8.2 Association Level Security

No additional association-level security is provided. All Calling AE Titles and internal network IP addresses are permitted.

8.3 Application Level Security

The *Oncospace Edge Agent* is secured using an Azure Function key that is provided once at application start-up. The key is encrypted and stored using DPAPI such that it does not need to be provided for subsequent start-ups. Access to the API provided to the TPS by the Edge Agent is secured using a certificate obtained from the Cloud by the Edge Agent during startup.

8.4 Basic Application Level Confidentiality Profile

The *Oncospace Edge Agent* removes patient identification from images prior to image upload. No DICOM instances, de-identified or otherwise, are kept on local storage (they are maintained in live memory only and deallocated after upload).

The anonymization process maintains the study/series/image hierarchy of the original images, and any cross references that may exist between images. It does this by using a complex (slow) but deterministic one-way hashing algorithm, with a hash salt specific to each customer.

Note: A configurable list of one or more PHI elements, including Patient ID and Patient Name, may be encrypted by the Edge Agent and passed to the *Dedicated Cloud Services* for the Customer. This process occurs via a secure RESTful interface, and the data is further transformed upon arrival in the Cloud, using a second encryption key. These operations do not use the DICOM protocol and are described in other Oncospace security documentation.

The following table describes which DICOM tags are removed or modified during anonymization. All other tags (defined in the DICOM 3.0 data dictionary) are left unchanged. Private tags are removed by the de-identification process. The application removes, re-maps, nulls (empty value), or adjusts the required attributes as specified in DICOM PS 3.15 Table E.1-1. The application does not add or modify the Patient Identity Removed (0012,0062) attribute since it is impossible to determine whether the image pixel data has been de-identified.

The *Oncospace System* does not support DICOM de-identification profiles in communication between *Treatment Planning Systems* and the *Oncospace Edge Agent*. It is assumed that these AEs are co-located in a secure environment at the customer site.

Important: The following attributes are retained by the Oncospace System. Typically, these attributes do not contain PHI, but you must verify that this is the case. If not, notify Oncospace immediately and action can be taken to remove any such data and ensure that these attributes are no longer uploaded.

- (3006,0002) Structure Set Label (RT Structure Set IOD)
- (3006,0004) Structure Set Name (RT Structure Set IOD)
- (3006,0006) Structure Set Description (RT Structure Set IOD)
- (300A,0002) RT Plan Label (RT Plan IOD)
- (300A,0003) RT Plan Name (RT Plan IOD)
- (300A,0004) RT Plan Description (RT Plan IOD)

The specific attributes removed from the images conform to those specified in the DICOM Part 15 Annex E, Basic Application Level Confidentiality Profile, with the Confidentiality Options selected as follows:

Confidentiality Option	Oncospace Implementation
E.3.1 Clean Pixel Data Option	Not implemented – CT images shall not contain burned-in annotations with patient-identifying information. Instances where “Burned in Annotation (0028,03010) is present and equal to “YES” are rejected by the <i>Oncospace Edge Agent</i> .
E.3.2 Clean Recognizable Visual Features Option	Not implemented. The unsmoothed surface meshes generated by the Oncospace System are extremely difficult to associated with a patient.
E.3.3 Clean Graphics Option	Implemented (however graphics are not normally present on CT Image instances)
E.3.4 Clean Structured Content Option	Not applicable (not a structured report)
E.3.5 Clean Descriptors Option	Implemented. This includes removal of equipment identification, names of clinicians and operators, and institution identifiers.
E.3.6 Retain Longitudinal Temporal Information – Modified Dates	Not retained, except for the following dates that are retained unmodified. The associated Time attributes are not kept: <ul style="list-style-type: none"> • Structure Set Date (3006,0008) • RT Plan Date (300A,0006)
E.3.6 Retain Longitudinal Temporal Information – Modified Dates	Not retained – see line above for behavior
E.3.7 Retain Patient Characteristics Option	Not retained. Patient ID is transformed to a one-way hashed string using a complex (slow) hash with a secure hashing salt specified to the customer. All other attributes, including Patient Name are removed or replaced with dummy values.
E.3.8 Retain Device Identity Option	Not retained. This includes the removal of Institution information.
E.3.9 Retain UIDs Option	Not retained. UIDs are transformed into new UIDs, with consistency of new UIDs across the study maintained. Mapping to original UIDs not maintained (one-way hashing is used).
E.3.10 Retain Safe Private Option	Not required. All private attributes are removed.

9 ANNEXES

9.1 IOD Contents

9.1.1 *Created SOP Instances*

None.

9.1.2 *Usage of Attributes from Received IODs*

Over and above the constraints of the DICOM standard itself, the following attributes are required to be present:

- All IODs: Patient ID must be valued. Study Instance UID must have the same value across all CT Images and RT Instances in the patient data set. One Content Date and Content Time, Acquisition Date and Acquisition Time, or Instance Creation Date and Instance Creation Time being valued is recommended.
- RT Structure Set: Pertinent radiation targets and Organs at Risk (OARs) must be defined, with their geometry defined as contours.
- RT Plan: Sufficient beams and dosimetry information must be present for the Oncospace System to map onto a treatment protocol.
- RT Dose: Spatial dose information (a dose grid) must be present and have correct scaling.

9.1.3 *Attribute Mapping*

Not applicable – only DICOM storage is implemented.

9.1.4 *Coerced/Modified Fields*

None.

9.2 Data Dictionary of Private Attributes

Oncospace System does not create private attributes.

9.3 Coded Terminology and Templates

None.

9.4 Grayscale Image Consistency

Not Applicable.

9.5 Standard Extended/Specialized/Private SOP Classes

None.

9.6 Private Transfer Syntaxes

None.