



Cancer Pathology Implementation Guide

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Acronyms and Abbreviations Guide

DQA	Data Quality Assurance
DSA	Data Sharing Agreement
HIN	Health Information Network
HL7	Health Level Seven
MCSP	Michigan Cancer Surveillance Program
MDHHS	Michigan Department of Health and Human Services
MiHIN	Michigan Health Information Network Shared Services
MSH	Message Header
MU	Meaningful Use
MUCA	Master Use Case Agreement
NAACCR	North American Association of Central Cancer Registries
OID	Object Identifier
PHIN MS	Public Health Information Network Messaging System
TDSO	Trusted Data Sharing Organization
VPN	Virtual Private Network



Definitions

Applicable Laws and Standards. In addition to the definition set forth in the Data Sharing Agreement, the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2; the Michigan Mental Health Code, at MCLA §§ 333.1748 and 333.1748a; and the Michigan Public Health Code, at MCL § 333.5131, 5114a.

Common Gateway. The method by which data is sent and received by MiHIN using various national standard protocols (e.g. NwHIN SOAP, IHE XCA, IHE XDS.b).

Conforming Message. A message that is in a standard format that strictly adheres to the implementation guide for its applicable use case.

Data Sharing Agreement. Any data sharing organization agreement signed by both MiHIN and a participating organization. Data sharing organization agreements include but are not limited to: Qualified Data Sharing Organization Agreement, Virtual Qualified Data Sharing Organization Agreement, Consumer Qualified Data Sharing Agreement, Sponsored Shared Organization Agreement, State Sponsored Sharing Organization Agreement, Direct Data Sharing Organization Agreement, Simple Data Sharing Organization Agreement, or other data sharing organization agreements developed by MiHIN.

Electronic Address. A string that identifies the transport protocol and end point address for communicating electronically with a recipient. A recipient may be a person, organization or other entity that has designated the electronic address as the point at which it will receive electronic messages. Examples of an electronic address include a secure email address (Direct via secure SMTP) or secure URL (SOAP / XDR / REST / FHIR). Communication with an electronic address may require a digital certificate or participation in a trust bundle.

Electronic Service Information (ESI). All information reasonably necessary to define an electronic destination's ability to receive and use a specific type of information (e.g., discharge summary, patient summary, laboratory report, query for patient/provider/healthcare data). ESI may include the type of information (e.g. patient summary or query), the destination's electronic address, the messaging framework supported (e.g., SMTP, HTTP/SOAP, XDR, REST, FHIR), security information supported or required (e.g., digital certificate) and specific payload definitions (e.g., CCD C32 V2.5). In addition, ESI may include labels that help identify the type of recipient (e.g., medical records department).

End Point. An instance of an electronic address or ESI.

Exhibit. Collectively, a use case exhibit or a pilot activity exhibit.

Health Level 7 (HL7). An interface standard and specifications for clinical and administrative healthcare data developed by the Health Level Seven organization and approved by the American National Standards Institute (ANSI). HL7 provides a method



for disparate systems to communicate clinical and administrative information in a normalized format with acknowledgement of receipt

Health Information. Any information, including genetic information, whether oral or recorded in any form or medium, that (a) is created or received by a health provider, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and (b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health Information Network (HIN). An organization or group of organizations responsible for coordinating the exchange of protected health information (PHI) in a region, state, or nationally.

Health Plan. An individual or group plan that provides, or pays the cost of medical care (as “group health plan” and “medical care” are defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)). Health plan further includes those entities defined as a health plan under HIPAA, 45 C.F.R 160.103.

Health Professional means (a) any individual licensed, registered, or certified under applicable Federal or State laws or regulations to provide healthcare services; (b) any person holding a nonclinical position within or associated with an organization that provides or coordinates healthcare or healthcare related services; and (c) people who contribute to the gathering, recording, processing, analysis or communication of health information. Examples include, but are not limited to, physicians, physician assistants, nurse practitioners, nurses, medical assistants, home health professionals, administrative assistants, care managers, care coordinators, receptionists and clerks.

Health Provider means facilities/hospitals, health professionals, health plans, caregivers, pharmacists/other qualified professionals, or any other person or organization involved in providing healthcare.

Information Source. Any organization that provides information that is added to a MiHIN infrastructure service.

Master Use Case Agreement (MUCA). Legal document covering expected rules of engagement across all use cases. Trusted data sharing organizations sign master use case agreement one time, then sign use case exhibits for participation in specific use cases.

Meaningful Use. Using certified EHR technology to improve quality, safety and efficiency of healthcare, and to reduce health disparities as further contemplated by title XIII of the the American Recovery and Reinvestment Act of 2009.

Message. A mechanism for exchanging message content between the participating organization to MiHIN services, including query and retrieve.

Message Content. Information, as further defined in an Exhibit, which is sent, received, found or used by a participating organization to or from MiHIN services. Message content includes the message content header.



Message Header (“MSH”) or Message Content Header. The MSH segment present in every HL7 message type that defines the Message’s source, purpose, destination, and certain syntax specifics such as delimiters (separator characters) and character sets. It is always the first segment in the HL7 message, with the only exception being HL7 batch messages.

Michigan Cancer Surveillance Program. The program that operates the cancer registry for the State of Michigan. The cancer registry is connected to the MDHHS Data Hub.

Michigan Health Information Network Shared Services. The MiHIN for the State of Michigan.

MiHIN Infrastructure Service. Certain services that are shared by numerous use cases. MiHIN infrastructure services include, but are not limited to, Active Care Relationship Service (ACRS), Health Directory, Statewide Consumer Directory (SCD), and the Medical Information Direct GATEway (MIDIGATE®).

MiHIN Services. The MiHIN infrastructure services and additional services and functionality provided by MiHIN allowing the participating organizations to send, receive, find, or use information to or from MiHIN as further set forth in an exhibit.

Negative Acknowledgment (NAK or NACK). “Not acknowledged” and is used to negatively acknowledge or to reject previously received message content or to indicate some kind of error.

Notice. A message transmission that is not message content and which may include an acknowledgement of receipt or error response, such as an ACK or NACK.

Patient Data. Any data about a patient or a consumer that is electronically filed in a participating organization or participating organization participant’s systems or repositories. The data may contain protected health information (PHI), personal credit information (PCI), and/or personally identifiable information (PII).

Person Record. Any record in a MiHIN infrastructure service that primarily relates to a person.

Pilot Activity. The activities set forth in the applicable exhibit and typically includes sharing message content through early trials of a new use case that is still being defined and is still under development and which may include participating organization feedback to MiHIN to assist in finalizing a use case and use case and use case exhibit upon conclusion of the pilot activity.

Send / Receive / Find / Use (SRFU). Means sending, receiving, finding, or using message content. Sending involves the transport of message content. Receiving involves accepting and possibly consuming or storing message content. Finding means querying to locate message content. Using means any use of the message content other than sending, receiving and finding. Examples of use include consuming into workflow, reporting, storing, or analysis. Send/Receive/Find/Use (SRFU) activities must comply with Applicable Laws & Standards or State Administrative Code as that term is defined in this agreement and the data sharing agreement.



Service Interruption. A party is unable to send, receive or find message content for any reason, including the failure of network equipment or software, scheduled or unscheduled maintenance, general Internet outages, and events of force majeure.

Source System. A computer system, such as an electronic health record system, at the participating organization, that sends, receives, finds or uses message content or notices.

Transactional Basis. The transmission of message content or a notice within a period of time of receiving message content or notice from a sending or receiving party as may be further set forth in a specific exhibit.

Transitions of Care. The movement of a patient from one setting of care (e.g. hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, rehabilitation facility) to another setting of care and can include transfers within a healthcare organization.

Trusted Data Sharing Organization (TDSO). An organization that has signed any form of agreement with MiHIN for data sharing.

Use Case. (a) A use case agreement previously executed by a participating organization; or (b) the use case summary, use case exhibit and a use case implementation guide that participating organization or TDSO must follow to share specific message content with the MiHIN.

Use Case Exhibit. The legal agreement attached as an exhibit to the master use case agreement that governs participation in any specific use case.

Use Case Implementation Guide (UCIG). The document providing technical specifications related to message content and transport of message content between participating organization, MiHIN, and other TDSOs. use case implementation guides are made available via URLs in exhibits.

Use Case Summary. The document providing the executive summary, business justification and value proposition of a use case. Use case summaries are provided by MiHIN upon request and via the MiHIN website at www.mihin.org.



1. Introduction

1.1 Purpose of Use Case

Allows healthcare providers and pathology laboratories to submit electronic lab results containing electronic pathology reports through MiHIN.

To help keep consumers healthy and cancer-free, state cancer surveillance programs are tasked with monitoring the incidence of cancer. These programs work to help consumers prevent cancer while also encouraging recommended cancer screenings or tests to help detect cancer early.

Cancer pathology reports are an important and fundamental tool for cancer monitoring, service planning, and research. These reports are the primary method for identifying the rate of occurrence and impact of cancer in a population. Cancer information collected from pathology laboratories can be used to evaluate diagnosis and treatment strategies for an entire consumer population and for the Medicaid beneficiary population. Meaningful Use recognizes the importance of this information as a reportable measure.

Paper-based reporting has been used for most reportable infectious diseases and other laboratory findings, such as cancer pathology reports. Today, electronic reports allow hospitals and laboratories to send these cancer test results through automated and secure digital communication quickly and efficiently. Electronic lab reports allow timely reporting to public health agencies and help reduce reporting burdens in healthcare.

National cancer laboratories are currently able to send pathology information to state central cancer registries through the Public Health Information Network Messaging System (PHIN MS). State cancer registries are intended to enable monitoring the incidence of cancer, enable cancer control planning and allow assessment of progress toward goals relative to the state public health interventions.

However, Michigan is one of the few remaining states that does not receive electronic cancer pathology lab test results through PHIN MS. For the State of Michigan, this role is performed by the Michigan Cancer Surveillance Program. The health information network (HIN) transports this information through the Michigan Department of Health and Human Services (MDHHS) Data Hub to the state's Cancer Registry.

1.2 Message Content

For this use case, Message Content means HL7 2.xx, ORU^R01.



1.3 Data Flow and Actors

In this use case, MiHIN enables the transport of messages across Trusted Data Sharing Organizations (TDSOs) within MiHIN, called “Participating Organizations” in the diagram below.

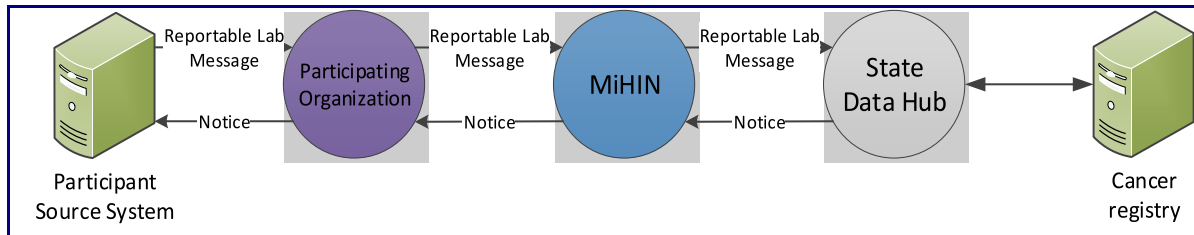


Figure 1. Data Flow for Cancer Pathology Reports

For more information about this use case, refer to the documents found on the following page:

<http://mihin.org/cancer-pathology/>



2 Standard Overview

2.1 Message Format

For sending Public Health Reporting messages to state registries, HL7 v2.5.1 or newer version of HL7 is preferred, however v2.3.1 is allowable.

2.2 Message Example

MiHIN is content-agnostic and does not validate content for this use case beyond the message header. To enter fully into production, messages must conform to the registry's implementation guide as well: [North American Association of Central Cancer Registries Implementation Guide for Pathology Laboratory Electronic Reporting](#). A message example is shown below:

```
MSH|^~\&||INDEPENDENTLABSERVICES^33D1234567^CLIA|||200506021339||ORU^
R01^ORU_R01|2004072813390045|P|2.5.1|||||VOL_V_3
0_ORU_R01^NAACCR_CP^2.16.840.1.113883.9.8^ISO
```

```
PID|1||000001125^^^SS~common key insertion area^^^CKS
~00466144^^^MR||Paulson^Ryan||19780319|M||2106-3^White^HL70005| 640 E
Hudson Circle^^St. Clair Shores^MI^48082^^H||||M ORC|RE|||||||Gift of
Mercy Hospital| 565 S Rhine Street^^Warren^MI^48093||565 S Rhine
Street^^Warren^MI^48082
```

```
OBR|1||06-123456-MH|22049-1^Flow Cytometry
Analysis^LN|||200505021212|||||200505311130|^Bone
marrow|^B.J.^Healing^^^M.D.|2033271605|||||200505311332||F|||||109772&PAT
HOLOGIST&QUINCY&&&Dr .&MD&&NPI
```

```
OBX|1|TX|22633-2^nature of specimen^LN||Bone marrow.||N||F|||200505021212
OBX|2|TX|22636-5^clinical history^LN||Evaluate for non-Hodgkin's lymphoma: ALL:
myelodysplastic syndromes: chronic Lymphoproliferative disorders, CLL. Prior therapy:
chemotherapy, Fludarabine more than one month ago. CBC report
received.||N||F|||200505021212
```

```
OBX|3|TX|22638-1^comments^LN||Correlation with a comprehensive bone marrow
morphology examination, CBC data/blood smear, and other relevant clinical and
laboratory data is recommended.||N||F|||200505021212
```

```
OBX|4|TX|22637-3^final diagnosis^LN||A small population of monoclonal B-cells
(Kappa) is present in the bone marrow. The antigenic profile is consistent with chronic
lymphocytic leukemia/small lymphocytic lymphoma
(CLL/SLL).||N||F|||200505021212
```

```
OBX|5|TX|22049-1^phenotype^LN||1. A monoclonal kappa B-cell population co-
expressing CD5 and CD23 is present. 2. -92% maturing myeloid elements are
present.||N||F|||20050502121
```

*Green-highlighted area above is common key insertion area



3 Onboarding Process

3.1 Initial Onboarding

For organizations to share data with MiHIN under this use case, the organization undergoes two onboarding processes simultaneously. The two onboarding processes are legal onboarding and technical connectivity onboarding. These may occur in parallel – i.e., the organization can review and complete legal agreements with MiHIN while simultaneously establishing and testing technical connectivity. To initiate these two parallel onboarding processes, notify MiHIN via <http://mihin.org/requesthelp/>.

3.1.1 Initial Legal Process

The first time an organization undergoes the legal onboarding process with MiHIN, the organization negotiates and enters into a master organization agreement and master use case agreement which then allows the organization to enter into one or more use cases via use case exhibits.

Once an organization has entered into a master organization agreement, the organization can enter into an unlimited number of use cases with MiHIN. All of MiHIN's use cases are available at:

<http://mihin.org/about-mihin/resources/>

3.1.2 Initial Technical Connectivity Process

MiHIN considers itself “transport agnostic” and offers multiple options for organizations to establish technical connectivity to transport data to MiHIN. Organizations should select one or more connectivity methods for message transport based on their technical capabilities, and put in a service request at www.mihin.org/requesthelp. Currently MiHIN accepts the following transport methods:

- LLP over IPsec VPN – Lower-Layer Protocol over Internet Protocol Security Virtual Private Network

For VPN connectivity two VPNs are required. A primary VPN will facilitate regular traffic. A secondary will be established for fail-over purposes.

Additional transport methods may be added in the future. These can include NwHIN, XCA, REST/RESTFUL APIs, FHIR, and others.

The following steps describe the technical onboarding process. However, MiHIN typically conducts “onboarding kickoff” meetings with new organizations to go through each of these steps in detail and answer any questions.

1. The organization selects one or more supported transport methods and establishes connectivity with MiHIN. This step varies based on the method selected:
 - a. LLP over IPsec VPN – MiHIN's site-to-site VPN request form must be completed, sent and approved by MiHIN. Send a request via www.mihin.org/requesthelp to obtain



the VPN request form. A pre-shared key is then exchanged between the organization and MiHIN to initialize the connection. The LLP over IPsec VPN is the most efficient transport for very high volumes of messages.

2. Test messages are sent by the organization to MiHIN.
 - a. All test messages must have a “T” in the Message Header – field 11
 - b. Test traffic is routed via MiHIN to the appropriate destination. For Cancer Pathology, the destination is the state Cancer Registry via the state data hub.
 - c. The end destination monitors for inbound test traffic and confirm receipt with MiHIN, which confirms with the organization.
3. For the Cancer Pathology Use Case, the state Cancer Registry deems the sending facility to have entered into Data Quality Assurance Status (DQA) once they have successfully received a properly formatted message from the sending facility via the organization through MiHIN.
 - a. Until completion of the DQA process, sending facilities should continue to dually send their Cancer Pathology reports through MiHIN as well as continuing to send using any current method.
4. The state Michigan Cancer Registry declares the sending facility to be at production status after another period of successful testing and exiting DQA status.
 - a. At this time, the sending facility may then send production messages through the participating organization to MiHIN. The sending facility now places a “P” (for production) value in the MSH-11 instead of the “T” used during testing.

3.2 Onboarding Additional Sending Facilities

When a participating organization wishes to onboard additional sending facilities, those facilities must first register with the cancer registry. Once successful, the registration information from the cancer registry, including the Facility ID Number, must be emailed via www.mihin.org/requesthelp.

The new sending facility should then begin sending test messages to the cancer registry in the same fashion as the initial facility as detailed in section 3.1.2. Test messages may be required to contain “T” value in MSH-11. This requirement is decided by the receiving organization.



4 Specifications

4.1 Message Trigger Events

The HL7 message type for cancer pathology is ORU and the trigger event is R01.

4.2 General Message Requirements

For general rules that apply to the entire message, refer to the [NAACCR Implementation Guide for Pathology Laboratory Electronic Reporting](#).

4.3 Specific Segment and Field Definitions

4.3.1 Segment 1 – Message Header

The definitions in the table below shall be conformed to by all HL7 messages communicating the message header segment.

Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
1	1	ST	R	1..1		00001	Field Separator	
2	4	ST	R	1..1		00002	Encoding Characters	
3	180	HD	R	1..1	0361	00003	Sending Application	
4	180	HD	R	1..1	0362	00004	Sending Facility	OID
5	180	HD	R	1..1	0361	00005	Receiving Application	MCSR
6	180	HD	R	1..1	0362	00006	Receiving Facility	MDHHS
7	26	TS	R	1..1		00007	Date/Time of Message	
8	40	ST	X	0..0		00008	Security	
9	7	CM	R	1..1	0076 0003	00009	Message Type	ORU^R01^ORU_R01
10	20	ST	R	1..1		00010	Message Control ID	Should be repopulated (rather than pass-through) for outbound message header
11	3	PT	R	1..1		00011	Processing ID	P when in production, T for testing
12	60	VID	R	1..1	0104	00012	Version ID	
13	15	NM	X	0..0		00013	Sequence Number	
14	180	ST	X	0..0		00014	Continuation Pointer	
15	2	ID	X	0..0	0155	00015	Accept Acknowledgment Type	



Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
16	2	ID	X	0..0	0155	00016	Application Acknowledgment Type	
17	2	ID	X	0..0		00017	Country Code	
18	16	ID	X	0..0		00692	Character Set	
19	60	CE	X	0..0			Principal Language of Message	
20	20	ID	X	0..0		00356	Alternate Character Set Handling Scheme	

4.3.2 All Remaining Segments

The message header is the only segment that MIHIN requires to be formatted in a certain way. As noted previously, please follow the registry specified standards for all remaining segment and field definitions: [NAACCR Implementation Guide for Pathology Laboratory Electronic Reporting](#).

5 Troubleshooting

5.1 Production Support

	Severity Levels			
	1	2	3	4
Description	Critical Impact/ System Down: Business critical software is down or critical interface has failed. The issue is impacting all production systems, causing all participating organizations' or other organizations' ability to function to be unusable.	Significant Business Impact: Software component severely restricted. Entire organization is unable to continue business functions, causing all communications and transfer of messages to be halted.	Partial Failure or Downtime: Program is useable and less significant features unavailable. The service is online, though may not working as intended or may not currently working as intended or may not currently be accessible, though other systems are currently available.	Minimal Business: A non-critical software component is malfunctioning, causing minimal impact, or a test system is down.
Example	All messages to and from MiHIN are unable to be sent and received, let alone tracked	MiHIN cannot communication (send or receive) messages between single or multiple participating organizations, but can still successfully communicate with other organizations.	Messages are lost in transit; messages can be received but not sent.	Additional feature requested.
Primary Initiation Method	Phone: (517) 336-1430	Phone: (517) 336-1430	Web form at http://mihin.org/requesthelp	Web form at http://mihin.org/requesthelp
Secondary Initiation Method	Web form at http://mihin.org/requesthelp	Web form at http://mihin.org/requesthelp	Email to help@mihin.org	Email to help@mihin.org
Tertiary Initiation Method	Email to help@mihin.org	Email to help@mihin.org	N/A	N/A
Initial Response	Within 2 hours	Within 2 hours	1 business day	1 business day
Resolution Goal	24 hours	24 hours	3 business days	7 business days

A list of common questions regarding the Cancer Pathology Use Case can be found at:

<https://mihin.org/cancer-pathology-2/>

If you have questions, please contact the MiHIN Help Desk:

- www.mihin.org/requesthelp
- Phone: (517) 336-1430
- Monday – Friday 8:00 AM – 5:00 PM (Eastern)



6 Legal Advisory Language

This reminder applies to all use cases covering the exchange of electronic health information:

The Data Sharing Agreement (DSA) establishes the legal framework under which participating organizations can exchange messages through the MiHIN Platform, and sets forth the following approved reasons for which messages may be exchanged:

- a. By health care providers for Treatment, Payment and/or Health Care Operations consistent with the requirements set forth in HIPAA
- b. Public health activities and reporting as permitted by HIPAA and other Applicable Laws and Standards
- c. To facilitate the implementation of “Meaningful Use” criteria as specified in the American Recovery and Reinvestment Act of 2009 and as permitted by HIPAA
- d. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual’s personal representative in accordance with HIPAA
- e. By Data Sharing Organizations for any and all purposes, including but not limited to pilot programs and testing, provided that such purposes are consistent with Applicable Laws and Standards
- f. For any additional purposes as specified in any use case, provided that such purposes are consistent with Applicable Laws and Standards

Under the DSA, “**Applicable Laws and Standards**” means all applicable federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, regulations and judicial or administrative decisions promulgated by any governmental or self-regulatory agency, including the State of Michigan, the Michigan Health Information Technology Commission, or the Michigan Health and Hospital Association, as any of the foregoing may be amended, modified, codified, reenacted, promulgated or published, in whole or in part, and in effect from time to time. “Applicable Laws and Standards” includes but is not limited to HIPAA; the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2; the Michigan Mental Health Code, at MCLA §§ 333.1748 and 333.1748a; and the Michigan Public Health Code, at MCL § 333.5131, 5114a.

It is each participating organization’s obligation and responsibility to ensure that it is aware of Applicable Laws and Standards as they pertain to the content of each message sent, and that its delivery of each message complies with the Applicable Laws and Standards. This means, for example, that if a use case is directed to the exchange of physical health information that may be exchanged without patient authorization under HIPAA, the participating organization must not deliver any message containing health information for which an express patient authorization or consent is required (e.g., mental or behavioral health information).

Disclaimer: The information contained in this implementation guide was current as of the date of the latest revision in the Document History in this guide. However, Medicare and



Medicaid policies are subject to change and do so frequently. HL7 versions and formatting are also subject to updates. Therefore, links to any source documents have been provided within this guide for reference. MiHIN applies its best efforts to keep all information in this guide up-to-date. It is ultimately the responsibility of the participating organization and sending facilities to be knowledgeable of changes outside of MiHIN's control.

