Drug Pedigree 1.0 Conformance Requirements Document

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Abstract

The charter of the working group was to provide a standard, interoperable platform for supply chain partner compliance with state, regional and national drug pedigree laws. While this was the impetus of the work, there is nothing implicit in the deliverable that inhibits its use globally where a document pedigree is required. The conformance requirements contained herein are designed to ensure that the most common use cases are articulated and that the standard will effectively support those.

Status of this document

This section describes the status of this document at the time of its publication. Other documents may supersede this document. The latest status of this document series is maintained at the EPCglobal. This document has been reviewed by the working group and is in its final form of delivery to EPCglobal.

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1. Introduction

Testing an implementation of pedigree management software for conformance with the EPCglobal Drug Pedigree 1.0 Specification is fundamentally different from the testing of other EPCglobal specifications. Since this is a document specification, the user interfaces and programming interfaces are NOT part of the testing. The nature of this specification allows for focused testing on the output document within the specific set of input data and business process steps since the pedigree *document* must be interoperable between all implementations. The vendor interface implementations are inconsequential to the specification.

2. Scope

A Drug Pedigree Conformance Certification Program will focus on testing a given application's conformance to the Drug Pedigree 1.0 Specification. These test case requirements were developed by the EPCglobal SAG Drug Pedigree working group.

A Drug Pedigree Conformance Certification Program is NOT intended to test the performance, reliability, or scalability of the tested product.

3. Program Overview

The Drug Pedigree Certification Program will be offered by a certified testing laboratory to solution providers enrolled in the certification program.

Program Implementation and Certificate definition are to be defined by EPCglobal US and a chosen Testing Laboratory.

The conformance tests may not be exhaustive, but should be representative of capabilities needed for a successful Drug Pedigree implementation. The tests should be defined to be platform independent, and should not require products to be implemented on any particular system or platform.

4. Terminology

This document adopts terminology developed by the World Wide Web Consortium [W3C-Conformance]:

Certificate Issuer The organization that issues certificates of conformance, namely, EPCglobal.

Testing Laboratory An organization that carries out certification testing on behalf of the Certificate Issuer

Specification An EPCglobal specification for which conformance is tested.

Implementation Under Test (IUT) A submission of hardware and/or software for which certification is sought by an EPCglobal subscriber.

System Under Test (SUT) The IUT together with any other apparatus required to carry out the test.

Test Method A description of the test that is applied to the SUT. There may be more than one Test Method available for a given Drug Pedigree 1.0 specification requirement, each providing a different level of conformance testing.

Test Report Quoting from [W3C-Conformance]: "A Test Report contains the results of the testing effort. The test report should provide enough information that, if necessary, the testing effort could be duplicated. The testing report should contain:

- a complete description of the IUT,
- the name of the Testing Laboratory,
- the signature of a Testing Laboratory official,
- the date that the testing was completed,
- the name and version number of the Test Method
- the results of the Test Method
- an unambiguous statement indicating pass or fail."

Drug Pedigree Conformance Certification Program An EPCglobal US sponsored Software/Hardware solution certification program measuring Drug Pedigree 1.0 conformance.

Certificate of Conformance Quoting from [W3C-Conformance]: "The certificate of conformance is typically a summation of the Test Report. Since it is often used in the procurement process, it includes information most pertinent between the buyer and the seller."

5. Submission Requirements

[defined by EPCglobal and the Testing Lab]

6. Test Protocols

[defined by EPCglobal and the Testing Lab]

7. Drug Pedigree 1.0 Functional Requirements

The Drug Pedigree 1.0 Specification defines specific functionality that a valid Drug Pedigree Implementation must provide. The following tables outline the specific requirements that must be tested as defined by the Drug Pedigree 1.0 specification. Each test requirement entry references the Drug Pedigree 1.0 Specification and the test case requirement (TCR) used to verify functionality as defined in section 8 of this document.

7.1. Mandatory Requirements Matrix

The following table outlines the mandatory requirements for a Drug Pedigree implementation as defined by the Drug Pedigree 1.0 Specification.

Req. No.	Protocol SubClause	Requirements (Requirements, Command, …)	Applies to (ref)	How Verified (by Demonstration or by Design)
M1	6.1	X.509 certificates SHALL be used for the Electronic Pedigree		Demonstration
M2	6.2	The electronic pedigree digital signature processes SHALL conform to the X.509 certificate profile defined in the EPCglobal Certificate Profile version 1.0.		Demonstration
M3	6.2	Certain attributes SHALL be included in the certificate to provide this uniqueness.		Demonstration
M4	6.2	To ensure users can be uniquely identified when digitally signing electronic pedigrees, user certificates SHALL include the minimum attributes specified in Section 3.2.1 of the EPCglobal Certificate Profile version 1.0		Demonstration
M5	6.2	Certificates SHALL also include the user's RFC822 email address in conformance with the profile requirements		Demonstration
M6	6.2	To ensure servers can be uniquely identified when digitally signing electronic pedigrees, server certificates SHALL include the server's FQDN in conformance with the profile requirements.		Demonstration
M7	6.3	The Signature Method SHALL support the use of FIPS 186-2. The RSA algorithm [2, 14] SHALL be supported.		Demonstration
M8	6.3	The Digest Method SHALL support the use of FIPS 186-2. SHA1 [2, 14] algorithm.		Demonstration
M9	6.3	The Exclusive C14N XML Canonicalization method, without comments, described in W3C Exclusive XML Canonicalization Version 1.0 [12] SHALL be employed for both canonicalization and transforms.		Demonstration
M10	6.3	The inclusive namespaces PrefixList attribute SHALL support prefixes in any order within the string.		Demonstration

M11	6.3	The inclusive namespaces PrefixList attribute SHALL support arbitrary whitespace before, after and between the prefixes within the string		Demonstration
M12	6.3	Any inclusive namespaces SHALL contain the prefix of all namespaces that are in-scope and desired to be protected, but not visibly utilized, for the element being signed and its descendants.		Demonstration
M13	6.3	Any inclusive namespaces SHALL contain the string "#default" if a default namespace is in-scope and desired to be protected, but not visibly utilized, for the element being signed and its descendants.		Demonstration
M14	6.3	The same-document URI reference SHALL be employed. See section 4.3.3.3 of http://www.w3.org/TR/xmldsig-core		Demonstration
M15	6.3	XPATH SHALL NOT be used for specifying references.		Demonstration
M16	6.3	The KeyInfo element SHALL be present in the Signature element.		Demonstration
M17	6.3	In the KeyInfo element the use of X.509 SHALL be employed.		Demonstration
M18	6.3	The KeyInfo element SHALL include one and only one X509Data element and it SHALL be the only element supported.		Demonstration
M19	6.3	The single X509Data element SHALL include one and only one X509IssuerSerial element that identifies the signer's certificate and one X509Certificate element that contains the signer's certificate.		Demonstration
M20	6.3	The validation of digital signatures applied to electronic pedigrees SHALL conform to the following requirements and the Certificate Profile referenced above.		Demonstration
M21	6.3	The core validation method described in section 3.2 of http://www.w3.org/TR/xmldsig-core SHALL be employed		Demonstration

M22	6.3	The signer's certificate SHALL be validated in accordance with section 6 of RFC 3280 [9].		Demonstration
M23	10	Conforming implementations SHALL use the pedigree schema for all input and output documents.		Demonstration
M24	10	All schema elements marked as "Yes" in the "Mandatory" column in the tables below SHALL be included in all pedigree documents		Demonstration
M25	10	The value supplied in these elements SHALL be non-null.		Demonstration
M26	10	All schema elements marked as "Conditional" in the "Mandatory" column in the tables below SHALL be included in pedigree documents that are subject to the situations that require them.		Demonstration
M27	10	The value supplied in these elements SHALL be non-null, unless the nillable attribute is explicitly set in the element.		Demonstration
M28	10	All schema elements marked as "No" in the "Mandatory" column in the tables below SHALL be optional in pedigree documents.		Demonstration
M29	10	Conforming implementations SHALL offer the Pedigree Envelope schema as an optional way to package one or more pedigree documents for transmission.		Demonstration
M30	10	All schema elements on incoming pedigrees and pedigree envelopes, regardless of marking, SHALL be accepted and handled properly. "Handled properly" CAN be interpreted as "ignored" for elements not marked as "Mandatory" or "Conditional".		Demonstration
M31	10	The schemas for the Pedigree and Pedigree Envelope are separate schemas and SHALL be versioned independently of each other.		Demonstration
M32	10	Enumerated lists included in the schema SHALL use the UpperCamelCase capitalization style for new items added to enumerated lists (e.g., ReceivedAndAuthenticated).		Demonstration

M33	10	If an enumeration is an acronym or contains an acronym, the acronym SHALL be specified in all uppercase (e.g., GLN).		Demonstration
M34	10.2	The innermost component of the pedigree SHALL always be contained in an `initalPedgiree` or a `repackagedPedigree` element.		Demonstration
M35	10.2	New pedigrees created by manufacturers or wholesalers for standard (non-repacked) prescription drug products SHALL always be started in an `intialPedigree` element.		Demonstration
M36	10.2	Pedigrees for repackaged or kitted products (where the kit has its own NDC) SHALL always be started in a `repackagedPedigree` element.		Demonstration
M37	10.2	The `pedigree` element is a wrapper element that contains a signed pedigree representing the prior chain of custody for an item. Information associated with each stage in a pedigree transaction in which ownership of an item passes from one supply chain partner to another SHALL be added to the pedigree in its own layer and then digitally signed by that supply chain partner.		Demonstration
M38	10.2	The `shippedPedigree` and `receivedPedigree` elements represent a stage (shipping or receiving) in a pedigree exchange transaction in which ownership of a product passes from one supply chain partner to another. These elements SHALL be used to wrap the preexisting pedigree for a product.		Demonstration
M39	10.2	Signatures SHALL be applied over `shippedPedigree` or `receivedPedigree` elements, signing over new content added to the pedigree and any prior pedigree content from previous transactions.		Demonstration

M40	10.2	At any given time, the outermost `pedigree` element SHALL contain a `shippedPedigree` and a `Signature` element, or a `receivedPedigree` and a `Signature` element.		Demonstration
M41	10.2	As each transaction occurs, the preexisting pedigree for an item SHALL be wrapped inside of a `pedigree` layer element.		Demonstration
M42	10.2.2	Carriage return and line feed characters SHALL NOT appear in any string elements.		Demonstration
M43	10.2.2.1	Information associated with each stage in a pedigree transaction in which ownership of an item passes from one supply chain partner to another SHALL be added to the pedigree in its own layer and then digitally signed by that supply chain partner.		Demonstration
M44	10.2.2.1	The very innermost `shippedPedigree` layer SHALL contain the starting point for the pedigree.		Demonstration
M45	10.2.2.1	The starting point for the pedigree SHALL always be an `initialPedigree` or a `repackagedPedigree` element.		Demonstration
M46	10.2.2.2	The `LayerType` elements SHALL be used to wrap the preexisting pedigree for a product.		Demonstration
M47	10.2.2.2	Signatures SHALL be applied over `LayerType` elements, signing over new content added to the pedigree and any prior pedigree content from previous transactions.		Demonstration
M48	10.2.2.2	At any given time, the outermost `pedigree` element SHALL contain a `shippedPedigree` and a `Signature` element, or a `receivedPedigree` and a `Signature` element.		Demonstration
M49	10.2.2.2	shippedPedigree - This layer element SHALL be added to the pedigree each time an exchange transaction occurs.		Demonstration

M50	10.2.2.2	receivedPedigree - This layer element SHALL be added to the pedigree each time a product is received as a result of an exchange transaction that requires that the pedigree be updated with the product receipt information and digitally signed.		Demonstration
M51	10.2.2.2	Signature - This element SHALL be added to the pedigree to sign over new content added in the preceding layer (shippedPedigree or receivedPedigree) in an exchange transaction.		Demonstration
M52	10.2.2.3	The `ShippedPedigreeType` element SHALL wrap the preexisting pedigree (e.g., an initial pedigree, an initial pedigree for repackaged products, an unsigned received pedigree, or a pedigree received with a prior chain of custody) and adds information about the current transaction to the pedigree.		Demonstration
M53	10.2.2.3	The very innermost `shippedPedigree` layer SHALL contain the starting point for the pedigree.		DUPLICATE WITH M44
M54	10.2.2.3	transactionInfo - This element SHALL be added to the pedigree each time an exchange transaction occurs.		Demonstration
M55	10.2.2.4	The `ReceivedPedigreeType` element SHALL wrap the preexisting pedigree and adds information about the receipt to the pedigree.		Demonstration
M56	10.2.2.4	`ReceivedPedigreeType -` This element SHALL be later signed.		Demonstration
M57	10.2.2.5	The BaseExtensibleType SHALL be used for extensibility of pedigree schema elements.		Demonstration
M58	10.2.2.5	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M59	10.2.2.5	serialNumber - This identifier SHALL be used to reference the pedigree by external systems.		Demonstration

M60	10.2.2.5	A new serial number SHALL be assigned each time the pedigree is updated and signed (in new shippedPedigree or receivedPedigree layer).		Demonstration
M61	10.2.2.6	serialNumber - This element SHALL be inserted into new initial pedigrees when they are first created.		Demonstration
M62	10.2.2.6	This element SHALL be referenced in new `repackagedPedigree` elements when the `repackagedPedigree` references an `initialPedigree` for a previous product.		Demonstration
M63	10.2.2.6	Software implementations SHALL accommodate pedigrees where this element is present and where it is not present.		Demonstration
M64	10.2.2.6	productInfo - This element SHALL be inserted in the pedigree when it is first created and SHALL occur only once.		Demonstration
M65	10.2.2.6	transactionInfo - This element SHALL be present when a wholesaler initiates the pedigree to record the transaction information from the sale from the manufacturer to the wholesaler.		Demonstration
M66	10.2.2.6	`receivingInfo -` This element SHALL be present when a wholesaler initiates the pedigree to record wholesaler's receipt information.		Demonstration
M67	10.2.2.6	altPedigree - This element SHALL be present when a wholesaler creates a pedigree based on a pedigree received that was in an alternate format.		Demonstration
M68	10.2.2.6	altPedigree - This element SHALL include the serialNumber element.		Demonstration
M69	10.2.2.6	wasRepackaged - This attribute SHALL be present and TRUE when an altPedigree represents a repackaged item.		Demonstration

M70	10.2.2.7	previousProducts - This element SHALL be repeated as many times as necessary to represent each product used to create the repackaged products.		Demonstration
M71	10.2.2.7	previousPedigrees - This element SHALL be repeated as many times as necessary to include the pedigree for each product used to create the repackaged products.		Demonstration
M72	10.2.2.7	previousPedigrees - This element SHALL be present when there is a regulatory requirement to include the source or “parent” pedigrees for the repackaged products.		Demonstration
M73	10.2.2.7	productInfo - This element SHALL be inserted in the pedigree when it is first created and occurs only once.		Demonstration
M74	10.2.2.8	The `UnsignedeceivedPedigreeType` element SHALL wrap the preexisting pedigree and add information about the receipt to the pedigree, but does not get signed.		Demonstration
M75	10.2.2.8	Id - This element SHALL be used to reference the element that will be signed.		Demonstration
M76	10.2.2.8	transactionInfo - This element SHALL be used only when a seller updates the pedigree with a return transaction from the customer back to the seller, and this element SHALL be used only when regulations allow the seller to update the pedigree on behalf of their customer.		Demonstration
M77	10.2.2.9	The BaseExtensibleType SHALL be used for extensibility of pedigree schema elements.		Demonstration
M78	10.2.2.9	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M79	10.2.2.11	The BaseExtensibleType SHALL be used for extensibility of pedigree schema elements.		Demonstration
M80	10.2.2.11	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration

M81	10.2.2.11	A singular pedigree SHALL contain only one `itemInfo` and the `quantity` element SHALL contain "1".		Demonstration
M82	10.2.2.11	There SHALL be only one `itemSerialNumber` element present if the item is serialized, and this element SHALL contain the serial number associated with the product.		Demonstration
M83	10.2.2.11	If the product does not have a serial number, the `itemSerialNumber` SHALL be omitted.		Demonstration
M84	10.2.2.11	An aggregate pedigree SHALL contain as many `itemInfo` elements as there are lot numbers represented by the pedigree.		Demonstration
M85	10.2.2.11	The `quantity` element for each lot number SHALL represent the number of items in the lot.		Demonstration
M86	10.2.2.11	Except for the following special case, an `itemInfo` SHALL be added to a pedigree each time a new transaction is added to the pedigree to record the items that are the subject of the transaction.		Demonstration
M87	10.2.2.11	expirationDate - This element SHALL be present when there is a regulatory requirement to include the expiration date on the pedigree.		Demonstration
M88	10.2.2.11	quantity - For serialized items, this quantity SHALL match the number of `itemSerialNumber` entries.		Demonstration
M89	10.2.2.11	itemSerialNumber - If the physical product unit does not have a serial number, the `itemSerialNumber` SHALL be omitted.		Demonstration
M90	10.2.2.11	The total number of `itemSerialNumber` elements SHALL match the number of items specified in the `quantity` element.		Demonstration
M91	10.2.2.11	This element SHALL be present when there is a regulatory requirement to include the serial number associated with the saleable product unit on the pedigree.		Demonstration

M92	10.2.2.11	This SHALL NOT apply to products that are not serialized.		Demonstration
M93	10.2.2.12	altTransactionIdentifier - This element SHALL be used if it is desired to provide more than one transaction identifier in the pedigree (e.g., both the PO Number and the Invoice Number for the transaction).		Demonstration
M94	10.2.2.12	transactionDate - The date associated with the `transactionIdentifier` (e.g., PO, Invoice, etc). This element SHALL be paired with the `transactionIdentifier` element.		Demonstration
M95	10.2.2.13	The BaseExtensibleType SHALL be used for extensibility of pedigree schema elements.		Demonstration
M96	10.2.2.13	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M97	10.2.2.13	shippingAddress - This element SHALL be present when there is a regulatory requirement to record the shipping address when it differs from the business address (this typically applies to both the sender business address and ship-from address and the recipient business address and ship-to address).		Demonstration
M98	10.2.2.13	licenseNumber - This element SHALL be present when there is a regulatory requirement to include the license information for the trading partner on the pedigree.		Demonstration
M99	10.2.2.13	contactInfo - This element SHALL be present when there is a regulatory requirement to include authenticator contact information on the pedigree.		Demonstration
M100	10.2.2.19	For signing information, name and title SHALL be present.		Demonstration
M101	10.2.2.19	For authenticator information, name, telephone, and email SHALL be present.		Demonstration

M102	10.2.2.19	The BaseExtensibleType SHALL be used for extensibility of pedigree schema elements.		Demonstration
M103	10.2.2.19	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M104	10.2.2.20	itemInfo - The items received SHALL be equal to or a subset of the items expressed in the `itemInfo` of the `shippedPedigree`.		Demonstration
M105	10.2.2.20	itemInfo - This element SHALL be repeated as many times as necessary to represent items received against each lot number represented by the pedigree for the product.		Demonstration
M106	10.2.2.20	The BaseExtensibleType SHALL be used for extensibility of pedigree schema elements.		Demonstration
M107	10.2.2.21	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M108	10.2.2.21	serialNumber - This element SHALL be inserted into new alternate pedigrees when they are first created.		Demonstration
M109	10.2.2.21	serialNumber - This element SHALL be referenced in new `repackagedPedigree` elements when the `repackagedPedigree` references an `altPedigree` for a previous product.		Demonstration
M110	10.2.2.21	mimeType - The MIME type of the content that SHALL be included with the pedigree specified in standard type/subtype representation (e.g., text/plain, application/pdf, image/jpeg).		Demonstration
M111	10.2.2.21	encoding - Only base 64 binary encoding is supported and the value of this element SHALL be base64binary.		Demonstration
M112	10.2.2.22	`PreviousProductType` - This element SHALL be repeated as many times as necessary to represent each product used to create the repackaged products.		Demonstration

M113	10.2.2.22	serialNumber - This element SHALL reference a serial number of an `intialPedigree`, `altPedigree`, or `pedigree` that is defined in the `previousPedigrees` element.		Demonstration
M114	10.2.2.22	serialNumber - Software implementations SHALL accommodate pedigrees where this element is present and where it is not present.		Demonstration
M115	10.2.2.22	previousProductInfo - This element SHALL be a cross-reference to the `productInfo:drugName` when the `previousProduct` references an `initialPedigree` or `pedigree`.		Demonstration
M116	10.2.2.22	itemInfo - The items referenced SHALL be equal to or a subset of the items expressed in the `itemInfo` of the parent pedigrees.		Demonstration
M117	10.2.2.22	itemInfo - This element SHALL be repeated as many times as necessary to represent items used in the repackaging against each lot number represented by the pedigree for the parent product.		Demonstration
M118	10.2.2.23	drugName - This element SHALL be a cross-reference to the `productInfo:drugName` when the `previousProduct` references an `initialPedigree` or `pedigree`.		Demonstration
M119	10.2.2.24	`PreviousPedigreeType` - This element SHALL be repeated as many times as necessary to represent each product used to create the repackaged products.		Demonstration
M120	10.2.2.24	pedigree - This element SHALL be used if the pedigrees were received in the standard electronic format.		Demonstration
M121	10.2.2.25	The `BaseExtensibleType` SHALL be used for extensibility of pedigree schema elements.		Demonstration

M122	10.2.2.25	Extensibility SHALL be only allowed in NameSpace ##other ensures that any extensibility in targetNameSpace goes through the normal EPCglobal vetting process.		Demonstration
M123	10.2.2.26	`EncodingType` - The value SHALL be "base64binary"		Demonstration
M124	10.2.2.27	If one of the NDC enumerations is used, the NDC SHALL be expressed as a contiguous string with no dashes separating the segments.		Demonstration
M125	10.2.2.31	The following table defines the elements that SHALL be signed when certifying pedigrees that support the self-authenticating pedigree model specified in pedigree regulations. 1) The `Signature` element signs the outermost `shippedPedigree` element, thereby signing the entire pedigree content, including prior pedigree transactions nested in the interior `Pedigree` element		Demonstration
M126	10.2.2.31	The following table defines the elements that SHALL be signed when certifying pedigrees that support the self-authenticating pedigree model specified in pedigree regulations. 2) The `Signature` element signs the outermost `receivedPedigree` element, thereby signing the receiving information added and the prior pedigree transactions nested in the interior `Pedigree` element.		Demonstration
M127	10.3	The pedigree envelope SHALL be a schema available to the user as an option.		Demonstration
M128	10.3.2.1	The BaseExtensibleType SHALL be used for extensibility of pedigree envelope schema elements.		Demonstration
M129	10.3.2.1	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration

M130	10.3.2.1	serialNumber - This identifier SHALL be expressed using a UUID 128-bit identifier as defined in RFC 4122, including the “urn:uuid” namespace prefix.		Demonstration
M131	10.3.2.2	ContainerType - This information SHALL be optional in the pedigree envelope, and is intended to provide a standard approach to conveying pedigree matching information for products that are not individually serialized.		Demonstration
M132	10.3.2.2	The BaseExtensibleType SHALL be used for extensibility of pedigree envelope schema elements.		Demonstration
M133	10.3.2.2	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M134	10.3.2.2	container - This element SHALL be used to express subcontainers that have pedigrees associated with items in those subcontainers.		Demonstration
M135	10.3.2.2	pedigreeHandle - If a pedigree represents multiple lots of the same product, a separate `pedigreeHandle` element SHALL be included for each unique lot represented by the pedigree.		Demonstration
M136	10.3.2.3	The BaseExtensibleType SHALL be used for extensibility of pedigree envelope schema elements.		Demonstration
M137	10.3.2.3	Extensibility SHALL be only allowed in NameSpace ##other.		Demonstration
M138	10.3.2.3	A `pedigreeHandle` element SHALL always include the pedigree `serialNumber`.		Demonstration
M139	10.3.2.3	If the products represented by the pedigree are serialized items, the `pedigreeHandle` SHALL include the `itemSerialNumber` for each serialized item represented by the pedigree.		Demonstration

M140	10.3.2.3	If the products represented by the pedigree are not serialized items, the `pedigreeHandle` MAY include the `prodctCode` and SHALL include the `quantity` and `lot` elements for the lot of product represented by the pedigree.		Demonstration
M141	10.3.2.3	If a pedigree represents multiple lots of the same product, a separate `pedigreeHandle` element SHALL be included for each unique lot represented by the pedigree.		Demonstration
M142	10.3.2.3	itemSerialNumber - This element SHALL be present only when the individual product items are serialized and SHALL be repeated multiple times, one for each item serial number.		Demonstration
M143	10.3.2.3	productCode - If present, this element SHALL reflect the `productCodes` enumerated in the `productCode` element of the corresponding pedigree.		Demonstration
M144	10.3.2.3	quantity - This element SHALL be present if the individual product items are not serialized.		Demonstration
M145	10.3.2.3	lot - This element SHALL be present if the individual product items are not serialized.		Demonstration
M146	10.3.2.4	The `BaseExtensibleType` SHALL be used for extensibility of pedigree envelope schema elements.		Demonstration
M147	10.3.2.4	Extensibility SHALL be only allowed in NameSpace ##other ensures that any extensibility in targetNameSpace goes through the normal EPCglobal vetting process.		Demonstration
M148	8	The ePedigree SHALL be captured and delivered as a single immutable document.		Demonstration
M149	8	The transfer of ePedigree documents SHALL conform to a push based transfer.		Demonstration

M150	8	The transfer SHALL occur via secure and, if transmitted over the public internet, authenticated mechanisms.		Demonstration
M151	8	If transmitted over the public internet, the transfer SHALL meet the expectation of Non-Repudiation.		Demonstration
M152	9.1	The “version” field of the documentInfo elements SHALL contain the date string that reflects the date of the schema XSD file used.		Demonstration
M153	9.1	The string SHALL be composed like this: CCYYMMDD Where CC is the century, “20” for example YY is the year, “06” for example MM is the month, “02” for example DD is the day of the month, “05” for example. The date string for the example pre-standard schema version would be “20060205”.		Demonstration
M154	9.1	The same technique SHALL be used to identify the use of this specific pedigree envelope schema version when creating production pedigree envelope documents prior to its adoption as a standard by EPCglobal or other body.		Demonstration
M155	9.1	The “version” field of the pedigreeEnvelope element SHALL contain the date string that reflects the date of the schema XSD file used.		Demonstration

M156	9.2	Once the pedigree and pedigree envelope schemas are adopted as a standard, the namespace SHALL be used to identify the major version.		Demonstration
M157	9.2	The “version” field of the documentInfo elements SHALL be used to identify minor releases between major versions.		Demonstration
M158	9.4	The Pedigree schema that is adopted as a standard SHALL be backwards compatible with the pre-standard interim version of the Pedigree schema.		Demonstration
M159	9.4	The Pedigree schema that is adopted as a standard SHALL support nesting of pedigrees created with the pre-standard interim version of the Pedigree schema within one of the pedigree LayerTypes and SHALL maintain the integrity of the digitally signed content of the interim pedigree layers.		Demonstration
M160	9.4	Pedigrees and pedigree envelopes created using this Standard (after the interim version) SHALL express pedigree and envelope serial numbers using the UUID in URN format using an xs:string element per RFC 4122.		Demonstration
M161	9.4	Implementations SHALL support pedigree and pedigree envelope serial numbers with and without the “urn:uuid” namespace prefix to preserve backwards compatibility to pedigrees generated prior to the release of the Standard.		Demonstration
M162	9.5.1	Pedigree implementations SHALL support nesting of pedigrees with an older minor version of the Pedigree schema within a new pedigree LayerType that is of a newer minor version of the Pedigree schema, within the same major version of the Pedigree schema.		Demonstration

M163	9.5.2	Pedigree implementations SHALL support nesting of pedigrees with an older major version of the Pedigree schema within a new pedigree LayerType that is of a newer major version of the Pedigree schema.		Demonstration
M164	9.5.3	Pedigree implementations SHALL support nesting of pedigrees with a newer minor version of the Pedigree schema within a new pedigree LayerType that is of an older minor version of the Pedigree schema, within the same major version of the Pedigree schema.		Demonstration
M165	9.5.4	Pedigree implementations SHALL NOT allow nesting of new layers to pedigrees that already contain layers that use a newer major version of the Pedigree schema when the new pedigree layer would use an older major version of the Pedigree schema.		Design
M166	9.5.4	At the time the major new version is adopted the EPCglobal work group shall publish the date based on this estimate as the first date that trading partners SHALL be able to receive pedigrees based on the new major schema version.		Design
M167	9.5.4	Trading partners SHALL NOT create pedigrees based on the new major schema version prior to that date even if their software is fully upgraded early.		Demonstration
M168	10.3.2.2	ContainerCode - If case serialization information is not available this element MAY represent a “null” value. The “null” value SHALL be represented using XML schema's nil mechanism (e.g., `<containerCode xsi:nil="true"></containerCode>`).		Demonstration

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7.2. Optional Requirements Matrix

The following table outlines those functional requirements that are defined as optional by the Drug Pedigree Specification

Req. No.	Protocol SubClause	Requirements (Requirements, Command, …)	Applies to (ref)	How Verified (by Demonstration or by Design)
O1				
O2				

8. Test Case Requirements

A Drug Pedigree Conformance Certification Program will test an Implementation Under Test (IUT) according to predefined test case requirements that have been designed to isolate and test specific features and functions of the Drug Pedigree 1.0 Specification.

Following table outlines the test scenarios and test numbers those are covered under those scenarios.

No.	Test Scenario	Test numbers
1	Manufacturer sells drugs to wholesaler and wholesaler distributes these drugs to retailers.	TCR-01, TCR-02, TCR-03
2	Repackager initiates pedigree flow for a repackaged product (Product B) after repackaging the source product (Product A).	TCR-04, TCR-05
3	Kit manufacturer creates a Kit called Kit A which includes three products, Product A, Product B and Product C. Regulations requires pedigrees for Product A and Product B to be included in the kit pedigree. But there is no regulatory requirement for Product C. Kit manufacturer then sells this kit to wholesaler.	TCR-06, TCR-07
4	Wholesaler ships partial amount from inbound pedigree (non-serialized)	TCR-08

5	Wholesaler ships all product from inbound pedigree (non-serialized)	TCR-09
6	Wholesaler ships partial amount from inbound pedigree (serialized)	TCR-10
7	Wholesaler ships all product from inbound pedigree (serialized)	TCR-11
8	Wholesaler receives signed pedigree from manufacturer and certifies for receipt of full quantity.	TCR-12, TCR-P13
9	Wholesaler receives signed pedigree from manufacturer and certifies for receipt of partial quantity.	TCR-P14, TCR-P15
10	Wholesaler receives signed pedigree from manufacturer and updates with receipt information without applying a signature.	TCR-16, TCR-17
11	Wholesaler updates pedigree with receipt information on behalf of customer for a return transaction without applying a signature.	TCR-18
12	Backwards compatibility between major versions of schema.	TCR-19
13	Mapping for a Pedigree Referring to Products in a Single Serialized Case	TCR-20
14	Mapping for a Pedigree Referring to Products in a Multi Serialized Case	TCR-21
15	No Mapping for a Pedigree Referring to Products Case	TCR-22
16	Mapping for a Pedigree Referring to Products in a Non Serialized Case	TCR-23

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8.1. Test Scenario – 1: Manufacturer sells drugs to wholesaler and wholesaler distributes these drugs to retailers.

8.1.1. Test Data

Following table contains sample data for manufacturer while initiating a pedigree for product A and selling it to wholesaler.

Data Elements	**Data Value**
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC442
Product Code Value	“3333-0014-06”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“1000”
Item Info	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	4
Item Serial Number	“00012345”
Item Serial Number	“00012346”
Item Serial Number	“00012347”
Item Serial Number	“00012348”
Sender Info/ Business Address	
Business Name	“Acme Laboratories”
Street Address1	“321 Main Street”
City	“Anytown”
State	“NJ”
Postal Code	“01900”
Country	“USA”
License Number	“NJ3333”

State	“NJ”
Agency	“DOH”
Contact Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	purchase order number
Transaction Type	Sale
Transaction Date	08/21/2006
Alternate Transaction Identifier	03333
Alternate Transaction Identifier Type	Invoice number
Signature Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”

Signature Meaning	Certified	

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195 The following table contains sample test data for wholesaler to use while selling product
196 bought from Acme lab to retailer.

Data Elements	**Value**
Sender Info/ Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL4444”
State	“FL”
Agency	“DOH”
Contact Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Recipient Info / Business Address	
Business Name	“Retail Pharmacy”
Street Address1	“7890 Grand Road”
City	“Sometown”
State	“FL”
Postal Code	“10101”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”

Transaction Identifier	
Identifier	“01111”
Transaction Identifier Type	ShippingNumber
Transaction Type	Sale
Transaction Date	08/21/2006
Item Info	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	1
I tem Serial Number	“00012345”
Signature Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Signature Meaning	Certified

8.1.2. Test Cases

8.1.2.1. Test Case Requirement - Verification of InitialPedigree element and its content for serialized products when pedigree is initiated by Manufacturer

TPId: TCR-01
Requirement Purpose: To verify that the InitialPedigree and its content comply with the specification when the electronic pedigree for serialized product is initiated by Manufacturer. **Requirement Tested:** M32, M33, M34, M35, M45, M61, M64, M85, M86, M87, M88, M90, M124
IUT role: Manufacturer.
Pre-test conditions: • IUT is running and operational.

• Provide Test Data to IUT to initiate a pedigree. • Test Data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from manufacturer to wholesaler. • Regulation requires expiration date to be included in the pedigree.		
Step	**Step description**	**Expected results**
1	Provide Test Data to IUT in supported format. Test Data should contain the information required for this test.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. InitialPedigree that contains the desired serial number, product info and item info. 2. Product info (inside the InitialPedigree) that contains desired drug name, manufacturer name, dosage, strength, container size and single or multiple entries of product code. 3. Product code value (inside productCode) is a contiguous string 4. Item info (inside the InitialPedigree) that contains the lot number, expiration date, quantity and item serial numbers. The total number of itemSerialNumber elements should match the number of items specified in the quantity element.

8.1.2.2. Test Case Requirement - Verification of backward compatibility with interim schema supported by IUT

TPId: TCR-02

Requirement Purpose: To verify that IUT supports backward compatibility with interim schema. Backward compatibility is tested by receiving a pedigree into IUT which is of interim version and continuing that pedigree by adding new pedigree layer to it using current schema version. **Requirement Tested:** M63		
IUT role: Wholesaler		
Pre-test conditions: • IUT is running and operational. • IUT should use a standard schema version which is newer than "20060418". • Provide Test Data to IUT to create a pedigree. • Test Data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from wholesaler to retailer.		
Step	**Step description**	**Expected results**
1	Send a pedigree to IUT representing sale of drugs from manufacturer to wholesaler, initiated by manufacturer. This pedigree should be created using pedigree schema version "20060418".	Demonstrate that pedigree is received by IUT.
2	Provide Test Data to IUT to continue the pedigree received in step 1 above. This Test Data represents sale of drugs from wholesaler to retailer with quantity of drugs remaining same as received from manufacturer. Use data listed in scenario 1. Provide data in the format supported by IUT. Use current pedigree version to create this new layer of pedigree representing sale from wholesaler to retailer.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. InitialPedigree that contains the product info and item info. serialNumber element should not be present in InitialPedigree. 2. DocumentInfo (inside innermost shippedPedigree) that contains version string "20060418".

8.1.2.3. Test Case Requirement - Verification of InitialPedigree element and its content when pedigree is initiated by Wholesaler

TPId: TCR-03

Requirement Purpose: To verify that the InitialPedigree and its content comply with the specification when the electronic pedigree is initiated by Wholesaler. **Requirement Tested:** M65, M66, M93, M94		
IUT role: Wholesaler		
Pre-test conditions: • IUT is running and operational. • Provide Test Data to IUT to create a pedigree. • Test Data should contain enough information necessary to describe the sale from manufacturer to wholesaler and to create a complete shipped pedigree to represent a sale of drugs from wholesaler to retailer. • Regulation requires more than one transaction identifier to be included in the pedigree.		
Step	**Step description**	**Expected results**
1	Provide Test Data to IUT in supported format. Test Data should contain the information required for this test.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. InitialPedigree that contains the desired serial number, product info, item info, transaction info and receiving info. 2. TransactionInfo that contains sender info, recipient info, transaction identifier, transaction type, transaction date and altTransactionIdentifier. 3. ReceivingInfo that contains date of receipt and information about received items.

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212

8.2. Test Scenario – 2: Repackager initiates pedigree flow for a repackaged product (Product B) after repackaging the source product (Product A)

8.2.1. Test Data

The following table contains sample data for Repackager to use while repackaging a source product A

Data Elements	Data Value
Data for Previous Product	
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC442
Product Code Value	“3333-0014-06”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“1000”
Item Info	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	100
Transaction Info/ Sender Info/ Business Address	
Business Name	“Acme Laboratories”
Street Address1	“321 Main Street”
City	“Anytown”
State	“NJ”
Postal Code	“01900”
Country	“USA”
License Number	“NJ3333”
State	“NJ”
Agency	“DOH”
Contact Info	
Name	“John Brown”

Title	“ Manager”
Telephone	“800-521-6010”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Recipient Info/ Business Address	
Business Name	“Big Repackager”
Street Address	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL6666”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“01111”
Transaction Identifier Type	Shippingnumber
Transaction Type	Sale
Transaction Date	08/21/2006
Repackaged Product Information	
Drug Name	“Product B”
Manufacturer	“Big Repackager”
Product Code Type	NDC442
Product Code Value	“3333-0014-07”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“100”
Item Info	
Lot	“1234-B”
Expiration Date	05/01/2016
Quantity	1000

219 Following data is a sample data for Repackager to use while shipping product B to
220 wholesaler.

Data Elements	Value
Item Info	
Lot	“1234-B”
Expiration Date	05/01/2016
Quantity	1000
Transaction Info /Sender Info/ Business Address	
Business Name	“Big repackager”
Street Address1	“456 Town Road”
Street Address2	N/A
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL4444”
State	“FL”
Agency	“DOH”
Contact Info	
Name	“Sally Miller”
Title	“Shipping Manager”
Telephone	“800-521-6010”
Email	“smiller@bigrepackager.com”
URL	“www.bigrepackager.com”
Recipient Info/Business Address	
Business Name	“Major Wholesales”
Street Address1	“7890 Grand Road”
Street Address2	N/A
City	“Sometown”

Data Elements	Value
State	“FL”
Postal Code	“10101”
Country	“USA”
Shipping Address	Same as above
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	ShippingNumber
Transaction Type	Sale
Transaction Date	08/21/2006
Signature Info	
Name	“Sally Miller”
Title	“Shipping Manager”
Telephone	“800-521-6010”
Email	“smiller@bigrepackager.com”
URL	“www.bigrepackager.com”
Signature Meaning	Certified

221

222 The following table contains sample test data for wholesaler to use while selling product
223 B to retailer.

Data Elements	**Value**
Sender Info/ Business Address	
Business Name	“Major Wholesales”
Street Address1	“7890 Grand Road”
City	“Major City”
State	“FL”

Data Elements	Value
Postal Code	“10101”
Country	“USA”
License Number	“FL4444”
State	“FL”
Agency	“DOH”
Contact Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Recipient Info / Business Address	
Business Name	“Retail Pharmacy”
Street Address1	“7890 Grand Road”
City	“Sometown”
State	“FL”
Postal Code	“10101”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“01111”
Transaction Identifier Type	ShippingNumber
Transaction Type	Sale
Transaction Date	08/21/2006
Item Info	
Lot	“1234-B”
Expiration Date	05/01/2016

Data Elements	Value
Quantity	1
I tem Serial Number	“00012345”
Signature Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Signature Meaning	Certified

8.2.2. Test Cases

8.2.2.1. Test Case Requirement – Verification of RepackagedPedigree element and its content when pedigree flow is initiated by Repacker for a repackaged item

TPId: TCR-04		
Requirement Purpose: To verify that the RepackagedPedigree and its content comply with the specification when the electronic pedigree flow is initiated by Repacker for a repackaged item. **Requirement Tested:** M115, M118		
IUT role: Repacker.		
Pre-test conditions: • IUT is running and operational. • Provide Test Data to IUT to initiate a pedigree. • Test Data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from repacker to wholesaler. • Regulation requires previous pedigree to be included in the pedigree. • Manufacturer does not provide pedigree, Repackager initiates pedigrees for source products		
Step	**Step description**	**Expected results**

1	Provide Test Data to IUT in supported format. Test Data should contain the information required for this test.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. RepackagedPedigree that contains the desired previous products, previous pedigrees, product info and item info elements. 2. PreviousProducts (inside the RepackagedPedigree) that contains previous product info, item info, contact info and serial number. This serial number should match the serial number contained in InitialPedigree which is inside previousPedigrees 3. PreviousProductInfo that contains drug name, manufacturer name and product code. These drug name, manufacturer name and product code should match with the respective information contained in InitialPedigree which is inside previousPedigrees

8.2.2.2. Test Case Requirement – Verification of backward compatibility with interim schema supported by IUT

TPId: TCR-05
Requirement Purpose: To verify that IUT supports backward compatibility with interim schema when pedigree flow is initiated by Repacker for a repackaged item. Backward compatibility is tested by receiving a pedigree into IUT which is of interim version and continuing that pedigree by adding new pedigree layer to it using current standard version. **Requirement Tested:** M114

IUT role: Wholesaler		
Pre-test conditions: • IUT is running and operational. • IUT should use a standard schema version which is newer than "20060418". • Provide Test Data to IUT to create a pedigree. • Test Data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from wholesaler to downstream trading partner.		
Step	**Step description**	**Expected results**
1	Send a pedigree to IUT. This pedigree should be created using pedigree schema version "20060418" and should represent a sale of drugs from repacker to wholesaler.	Demonstrate that pedigree is received by IUT.
2	Provide a set of data to demonstrate that the pedigree received in step 1 can be continued by adding a new layer of pedigree to represent further sale from wholesaler to a downstream trading partner. Provide data input to IUT in supported format.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. RepackagedPedigree (inside innermost shippedPedigree) that contains the previous product info, product info and item info. SerialNumber should not be present inside previousProducts. 2. DocumentInfo (inside innermost shippedPedigree) that contains version string "20060418".

8.3. Test Scenario – 3: Kit manufacturer creates a Kit called Kit A which includes three products, Product A, Product B and Product C.

Regulations require pedigrees for Product A and Product B to be included in the kit pedigree. But there is no regulatory requirement for Product C. Kit manufacturer then sells this kit to wholesaler.

8.3.1. Test Data

Following table contains sample data for Kit manufacturer to use while preparing a Kit which includes three products A, B and C.

Data Elements	Data Value
Details of first source product A	
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC442
Product Code Value	“3333-0014-06”
Dosage form	Tablets
Strength	60 mg
Container size	10
Item Info	
Lot	“1234-A”
Expiration Date	05/01/2011
Quantity	“100”
Contact Info	
Name	“Jane Smith”
Title	“Manager”
Telephone	“800-521-6010”
Email	“jsmith@acme.com”
URL	“www.acme.com”
Details of second source product B	
Drug Name	“Product B”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC442
Product Code Value	“5896-0014-07”
Dosage form	Tablets
Strength	60 mg
Container size	10

Item Info	
Lot	“5678-B”
Expiration Date	05/01/2011
Quantity	“5”
Contact Info	
Name	“Jane Smith”
Title	“Manager”
Telephone	“800-521-6010”
Email	“jsmith@acme.com”
URL	“www.acme.com”
Details of third source product C	
Drug Name	“Product C”
Manufacturer	“Omega medical supplies”
Product Code Type	‘CatalogNumber’
Product Code Value	“229065-XZ”
Item Info	
Lot	“223”
Expiration Date	09/11/2015
Quantity	“5”
Contact Info	
Name	“Jane Smith”
Title	“Manager”
Telephone	“800-521-6010”
Email	“jsmith@acme.com”
URL	“www.acme.com”
Product Info for Kit	
Drug Name	“Kit A”
Manufacturer	“Kitting Inc.”
Product Code Type	KitNumber
Product Code Value	“Kit-9988-0077-00”
Dosage Form	“TABLETS”

Strength	“60 mg”
Container Size	“10”
Item Info	
Lot	“5678-C”
Expiration Date	05/01/2011
Quantity (of saleable units in transaction)	“15”

244

245 Following table contains sample data for selling Kit A to wholesaler.

Data Elements	Value
Item Info	
Lot	“5678-C”
Expiration Date	05/01/2011
Quantity (of saleable units in transaction)	“1”
Sender Info/ Business Address	
Business Name	“Kitting Inc.”
Street Address1	“789 Town Road”
City	“Kitting City”
State	“FL”
Postal Code	“10101”
Country	“USA”
Shipping Address	Same as business address
License Number	“FL4444”
State	“FL”
Agency	“DOH”
Contact Info	
Name	“Joe Doe”
Title	“Manager”

Data Elements	Value
Telephone	“800-521-6010”
Email	“jdoe@kittinginc.com”
URL	“www.kittinginc.com”
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
Shipping Address	SAME AS ABOVE
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“01111”
Identifier Type	Shipping Number
Transaction Type	Sale
Transaction date	08/21/2006
Signature Info/ Signer Info	
Name	“Joe Doe”
Title	“Manager”
Telephone	“800-521-6010”
Email	“jdoe@kittinginc.com”
URL	“www.kittinginc.com”
Signature Meaning	Certified

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8.3.2. Test Cases

8.3.2.1. Test Case Requirement - Verification of RepackagedPedigree element and its content when pedigree flow is initiated by Kit manufacturer for the kitted item

TPId: TCR-06		
Requirement Purpose: To verify that the RepackagedPedigree and its content comply with the specification when the electronic pedigree flow is initiated by Kit manufacturer for the kitted item. **Requirement Tested:** M36, M62, M70, M71, M72, M73, M81, M83, M92, M112, M113, M117, M118, M119		
IUT role: Kit manufacturer.		
Pre-test conditions: • IUT is running and operational. • Provide Test Data to IUT to initiate a pedigree. • Regulations requires pedigrees to be provided for source products A and B • Kit manufacturer initiates pedigrees for source products A and B • Test Data should contain enough information necessary to create a complete shipped pedigree to represent a sale of kit from Kit manufacturer to Wholesaler.		
Step	**Step description**	**Expected results**
1	Provide Test Data to IUT in supported format. Test Data should contain the information required for this test.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. RepackagedPedigree that contains the multiple previousProducts (three occurrences, each for product A,B and C), multiple previousPedigrees (two occurrences, each for product A and B), product info and item info elements. 2. Product info (inside the RepackagedPedigree) that contains desired drug name (kit name), manufacturer name, dosage, strength, container size and product code.

		3. Serial number of initialPedigree matches the serial number of previous products 4. InitialPedigree element for each source product has one occurrence of itemInfo element. 5. ItemInfo element for source products and Kit does not contain itemSerialNumber elements.

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252 **8.3.2.2. Test Case Requirement - Verification of**
253 **altPedigree element and its content**

TPId: TCR-07		
Requirement Purpose: To verify that the altPedigree and its content comply with the specification. **Requirement Tested:** M67, M68, M69, M109, M110, M111		
IUT role: Kit manufacturer.		
Pre-test conditions: • IUT is running and operational. • Provide Test Data to IUT to initiate a pedigree. • Test Data should contain enough information necessary to create a complete Shipped pedigree to represent a sale of kit from kit manufacturer to wholesaler. • Regulation requires previous pedigrees for Product A and Product B to be included in the pedigree. • Source products A and B has paper pedigrees provides by manufacturer • Kit manufacturer scans the paper pedigrees into PDF format and embeds them into repackage pedigree as per specification allowed EPC ePedigree standard • Use any sequence of string to represent a binary form of paper pedigree		
Step	**Step description**	**Expected results**
1	Provide Test Data to IUT in supported format. Test Data should contain the information required for this test.	Verify that a pedigree is received from IUT. Verify that the received pedigree contains the following items correctly: 1. RepackagedPedigree that contains

		the multiple previousProducts (three occurrences, each for product A,B and C), multiple previousPedigrees (two occurrences, each for product A and B), product info and item info elements. 2. PreviousPedigrees that contains altPedigree. 3. AltPedigree that contains wasRepackaged attribute, MIME type, encoding type, data and serial number. This serial number should match the serial number contained in respective previousProducts element which is inside repackagedPedigree. Encoding type should be base64 binary and MIME type should be application/pdf. The value of wasRepackaged should be false.

8.4. Test Scenario – 4: Wholesaler ships partial amount from inbound pedigree (non-serialized)

8.4.1. Test Data

Data Elements	Value
Wholesaler Name	w2 wholesales Inc
wholesaler business address	10 downing street, tampa FL, 89880 USA

Wholesaler shipping address	10 downing street, tampa FL, 89880 USA
wholesaler License Info	LicenseNumber: 78787879878798 State: Florida Agency: FL-DOH
wholesaler contact for shipping	Name: John fu Title: Distribution Manager Telephone: 9998889900 Email: jfu@w2.com
wholesaler signer info for receiver	name: David John Title: Rec Dock Manager email: djohn@w2.com tel : 878989909080 URl: www.w2.com
wholesaler signer info for shipping	name: lisa smith Title: shipping Manager email: lsmith@w2.com tel : 8989898990 URl: www.w2.com
Wholesaler sold the following Items (partial list from the pedigree) to Retailer	
Sold Drug Items Info	
Lot	1234-A
ExpirationDate	2016-05-01
quantity	200
item serial numbers	N/A
Retailer Information	
Name: Retail Pharmacy	
Retailer business address	7890 Grand Road, Sometown

	FL, 10101 USA
Wholesaler shipping address	7890 Grand Road, Sometown FL, 10101 USA
Transaction identifier	333333
Transaction identifier type	ShippingNumber
Transaction date	2006-12-21
Transaction Type	Sale

261

262

263 ## 8.4.2. Test Cases

264 ### 8.4.2.1. Wholesaler ships partial amount from inbound
265 pedigree (non-serialized)

266

Wholesaler ships partial amount from inbound pedigree (non-serialized)		
TPId: TCR-08		
Requirement Purpose: This Test Case Requirement confirms the pedigree system complies with specification relating to `ShippedPedigree` element and its contents when the electronic pedigree with non-serialized product is shipped by a wholesaler containing partial quantity from an inbound pedigree. **Requirements Tested**: M1-M22, M23-M33, M37-M41, M42-M43, M44, M49, M52, M54, M79-M92 (M88-M92 for serialized products only), M95-M103, M121-122, M125, M148-151		
Pre-test conditions: • Provide test data to for IUT to create a pedigree • Test data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from wholesaler to wholesaler or pharmacy		
Step	**Step description**	**Expected results**

1	Provide input data in the format supported by IUT. Input data should contain the data required for this test.	A Pedigree is generated
2	Analyze the outermost component of the pedigree and compare the elements and data against each of the requirements listed for this test case	`ShippedPedigree` in the outermost layer. `ShippedPedigree` and its content shall confirm to the requirements under test for this test case

267

268 ## 8.5. Test Scenario – 5: Wholesaler ships all product from
269 inbound pedigree (non-serialized)

270 ### 8.5.1. Test data

Data Elements	Value
Manufacturer Name	Acme Laboratories
Manufacturer Business address	321 Main Street Anytown NJ, 01900 USA
Manufacturer shipping address	321 Main Street Anytown NJ, 01900 USA
Drug name	NEXIUM CAPSULES
dosageForm	ORAL
Dosage Strength	40mg
Container size	15
Product code	58016*66915

Product code type	NDC
Product code	58016*66915
Product code type	NDC542
Drug Item infor	
Lot	1234-A
ExpirationDate	2016-05-01
Quantity	1000
item serial numbers	N/A
Transaction identifier	454343
Transaction identifier type	PurchaseOrderNumber
Transaction date	2006-08-21
Transaction Type	Other
manufacturer contact name	John Brown
Title	Shipping Manager
Telephone	888-231-1000
Email	johnbrown@acmelabs.com
wholesaler name	W1 wholesales Inc
wholesaler business address	1 hollywood Blvd Miami FL, 89809 USA
Wholesaler shipping address	1 hollywood Blvd Miami FL, 89809 USA
wholesaler License Info	LicenseNumber: Fl32848328 State: Florida Agency: DOH
wholesaler Authenticator info for shipping	name: John Doe

	Title: Pedigree Controller email: jdpc@w1.com tel : 900-555-2345
wholesaler signer info for shipping	name: John Doe Title: Shipping Manager email: jd@w1.com tel : 899999989890809 URL: www.w1.com
Wholesaler1 sold to	w2 wholesales Inc
wholesaler business address	10 downing street, tampa FL, 89880 USA
Wholesaler shipping address	10 downing street, tampa FL, 89880 USA
Transaction identifier	01111111
Transaction identifier type	ShippingNumber
Transaction date	2006-12-21
Transaction Type	Sale

8.5.2. Test Cases

8.5.2.1. Wholesaler ships all product from inbound pedigree (non-serialized)

Wholesaler ships all product from inbound pedigree (non-serialized)
TPId: TCR-09

Requirement Purpose: This Test Case Requirement confirms the pedigree system complies with specification relating to `ShippedPedigree` element and its contents when the electronic pedigree with non-serialized product is shipped by a wholesaler containing all product from an inbound pedigree. **Requirements Tested**: M1-M22, M23-M33, M37-M41, M42-M43, M44, M49, M52, M54, M79-M92 (M88-M92 for serialized products only), M95-M103, M121-122, M125, M148-151		
Pre-test conditions: • Provide test data to for IUT to create a pedigree • Test data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from wholesaler to wholesaler or pharmacy		
Step	**Step description**	**Expected results**
1	provide input data in the format supported by IUT. Input data should contain the data required for this test.	A Pedigree is generated
2	Analyze the outermost component of the pedigree and compare the elements and data against each of the requirements listed for this test case	`ShippedPedigree` in the outermost layer. `ShippedPedigree` and its content shall confirm to the requirements under test for this test case

8.6. Test scenario – 6: Wholesaler ships partial amount from inbound pedigree (serialized)

8.6.1. Test data

Data Elements	Value
Wholeslaer Name	w2 wholesales Inc
wholesaler business address	10 downing street, tampa FL, 89880

	USA
Wholesaler shipping address	10 downing street, tampa FL, 89880 USA
wholesaler License Info	LicenseNumber: 78787879878798 State: Florida Agency: FL-DOH
wholesaler contact for shipping	Name: John fu Title: Distribution Manager Telephone: 9998889900 Email: jfu@w2.com
wholesaler signer info for receiver	name: David John Title: Rec Dock Manager email: djohn@w2.com tel : 878989909080 URl: www.w2.com
wholesaler signer info for shipping	name: lisa smith Title: shipping Manager email: lsmith@w2.com tel : 8989898990 URl: www.w2.com
Wholesaler sold the following Items (partial list from the pedigree) to Retailer	
Sold Drug Items Info	
Lot	1234-A
ExpirationDate	2011-05-01
quantity	2
item serial numbers	00012341, 00012342.
Retailer Information	
Name: Retail Pharmacy	
Retailer business address	7890 Grand Road,

	Sometown FL, 10101 USA
Wholesaler shipping address	7890 Grand Road, Sometown FL, 10101 USA
Transaction identifier	444444
Transaction identifier type	ShippingNumber
Transaction date	2006-12-21
Transaction Type	Sale

8.6.2. Test Cases

8.6.2.1. Wholesaler ships partial amount from inbound pedigree (serialized)

Wholesaler ships partial amount from inbound pedigree (serialized)		
TPId: TCR-10		
Requirement Purpose: This Test Case Requirement confirms the pedigree system complies with specification relating to `ShippedPedigree` element and its contents when the electronic pedigree with serialized product is shipped by a wholesaler containing partial quantity from an inbound pedigree. **Requirements Tested**: M1-M22, M23-M33, M37-M41, M42-M43, M44, M49, M52, M54, M79-M92 (M88-M92 for serialized products only), M95-M103, M121-122, M125, M148-151		
Pre-test conditions: • Provide test data to for IUT to create a pedigree • Test data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from wholesaler to wholesaler or pharmacy		
Step	**Step description**	**Expected results**

1	Provide input data in the format supported by IUT. Input data should contain the data required for this test.	A Pedigree is generated
2	Analyze the outermost component of the pedigree and compare the elements and data against each of the requirements listed for this test case	`ShippedPedigree` in the outermost layer. `ShippedPedigree` and its content shall confirm to the requirements under test for this test case

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287

288 ## 8.7. Test scenario – 7: Wholesaler ships all product from
289 inbound pedigree (serialized)

290

291 ### 8.7.1. Test data

Data Elements	Value
Manufacturer Name	Acme Laboratories
Manufacturer Business address	321 Main Street Anytown NJ, 01900 USA
Manufacturer shipping address	321 Main Street Anytown NJ, 01900 USA
Drug name	NEXIUM CAPSULES
dosageForm	ORAL
Dosage Strength	40mg
Container size	15

Product code	58016*66915
Product code type	NDC
Product code	58016*66915
Product code type	NDC442
Drug Item infor	
Lot	1234-A
ExpirationDate	2011-05-01
quantity	4
item serial numbers	00012341, 00012342, 00012343, 00012344.
Transaction identifier	7888
Transaction identifier type	PurchaseOrderNumber
Transaction date	2006-08-21
Transaction Type	Other
manufacturer contact name	John Brown
Title	Shipping Manager
Telephone	888-231-1000
Email	johnbrown@acmelabs.com
wholesaler name	W1 wholesales Inc
wholesaler business address	1 hollywood Blvd Miami FL, 89809 USA
Wholesaler shipping address	1 hollywood Blvd Miami FL, 89809 USA
wholesaler License Info	LicenseNumber: Fl32848328 State: Florida Agency: DOH

wholesaler Authenticator info for shipping	name: John Doe Title: Pedigree Controller email: jdpc@w1.com tel : 900-555-2345
wholesaler signer info for shipping	name: John Doe Title: Shipping Manager email: jd@w1.com tel : 899999989890809 URL: www.w1.com
Wholesaler1 sold to	w2 wholesales Inc
wholesaler business address	10 downing street, tampa FL, 89880 USA
Wholesaler shipping address	10 downing street, tampa FL, 89880 USA
Transaction identifier	22222
Transaction identifier type	ShippingNumber
Transaction date	2006-12-21
Transaction Type	Sale

292

293 ## 8.7.2. Test Cases

294 ### 8.7.2.1. Wholesaler ships partial amount from inbound
295 pedigree (serialized)

Wholesaler ships all product from inbound pedigree (serialized)
TPId: TCR-11

Requirement Purpose: This Test Case Requirement confirms the pedigree system complies with specification relating to `ShippedPedigree` element and its contents when the electronic pedigree with serialized product is shipped by a wholesaler containing all product from an inbound pedigree. **Requirements Tested**: M1-M22, M23-M33, M37-M41, M42-M43, M44, M49, M52, M54, M79-M92 (M88-M92 for serialized products only), M95-M103, M121-122, M125, M148-151		
Pre-test conditions: • Provide test data to for IUT to create a pedigree • Test data should contain enough information necessary to create a complete shipped pedigree to represent a sale of drugs from wholesaler to wholesaler or pharmacy		
Step	**Step description**	**Expected results**
1	Provide input data in the format supported by IUT. Input data should contain the data required for this test.	A Pedigree is generated
2	Analyze the outermost component of the pedigree and compare the elements and data against each of the requirements listed for this test case	`ShippedPedigree` in the outermost layer. `ShippedPedigree` and its content shall confirm to the requirements under test for this test case

8.8. Test Scenario – 8: Wholesaler receives signed pedigree from manufacturer and certifies for receipt of full quantity

8.8.1. Test Data

Data Elements	**Data Value**
Extension Data in Document Info	
Extension data for date the document id was issued	Element name=”documentDate”, type=”xs:date” Value=2006-08-21
Product Info	

Data Elements	Data Value
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC542 or NDC442 or NDC541 or NDC532
Product Code Value	“3333-0014-06”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“1000”
Item Info	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	4
Sender Info/ Business Address	
Business Name	“Acme Laboratories”
Street Address1	“321 Main Street”
City	“Anytown”
State	“NJ”
Postal Code	“01900”
Country	“USA”
License Number	“NJ3333”
State	“NJ”
Agency	“DOH”
Sender Contact Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Sender Signature Info	

Data Elements	Data Value
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Signature Meaning	Certified
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	PurchaseOrderNumber
Transaction Type	Sale
Transaction Date	08/21/2006
Receiving Info	
Date Received	8/22/2006
Lot	“1234-A”
Quantity	4
Recipient Signature Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”

Data Elements	Data Value
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Signature Meaning	ReceivedAndAuthenticated
Pedigree Version Info for Default Test Case	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20061220
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for wholesaler received pedigree	20061220
Pedigree Version Info for Backwards Compatibility Test Case Only	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20060418
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for wholesaler received pedigree	20060418 or 20060331

8.8.2. Test Cases

8.8.2.1. Test Case Requirement - Verification of a pedigree received from manufacturer for non-serialized items with extension data and certified for receipt of full quantity

TPId: TCR-12
Requirement Purpose: To verify that the ReceivedPedigree and its content comply with the specification when the electronic pedigree for non-serialized product is received by a wholesaler from a manufacturer with extension data, updated by the wholesaler for receipt of the full quantity, and digitally signed. **Requirement Tested:** M23, M24, M25, M26, M27, M28, M30, M32, M33, M42,

M43, M46, M47, M48, M50, M51, M55, M56, M57, M58, M59, M60, M83, M89, M104, M121, M122, M126, M152, M153, M156, M157, M158, M160		
IUT role: Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create a pedigree. • Expiration date is a required element. • Manufacturer pedigree is for non-serialized items and contains extension data. • Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.		
Step	**Step description**	**Expected results**
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 5. Pedigree element with the pedigree major version specified in the namespace. (M23, M156, M157) 6. shippedPedigree element (inside the Pedigree element) with a unique id attribute. The minor version will be for the Interim version of the pedigree schema. (M24, M25, M160) 7. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in the version element. (M24, M25, 152, 153) 8. Extension data in the documentInfo element using the BaseExtensibleType containing the documentDate. (M57, M58, M121, M122)

		9. initialPedigree, itemInfo, transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. (M24, M25) 10. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer. (M24, M25)
2	IUT applies receiving information to pedigree and digitally signs pedigree.	Verify that the pedigree is updated with the receiving information for the full quantity receipt and that it is digitally signed. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace, and wrapping the new receivedPedigree and Signature elements. (M23, M25, M27, M156, M43, M48) 2. receivedPedigree element (inside the Pedigree element) with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. (M24, M25, M27, M46, M50, M55, M160) 3. documentInfo element (inside the receivedPedigree element) containing the unique pedigree serial number in URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. (M24, M25, M27, M42, M59, M60, M157, M158) 4. Complete Pedigree element for the

		pedigree that was received from the manufacturer in step 1 (inside the receivedPedigree element). (M23, M24, M25, M27, M55) 5. receivingInfo element (inside the receivedPedigree element) containing the dateReceived and itemInfo elements. The itemInfo element contains the lot, expirationDate and quantity elements. (M24, M25, M26, M27, M42, M83, M89, M104) 6. signatureInfo element (inside the receivedPedigree element) containing the signerInfo, signatureDate and signatureMeaning elements. The signerInfo contains the name and title elements. (M24, M25, M26, M27, M28, M30, M32, M33, M42) 7. Signature element (inside the Pedigree element and signing the receivedPedigree element) containing SignedInfo, SignatureValue, and KeyInfo elements. The SignedInfo element contains the CanonicalizationMethod, SignatureMethod, and Reference elements. The Reference element contains the Transforms, DigestMethod and DigestValue elements. The KeyInfo element contains the X509Data element, with an X509IssuerSerial and X509Certificate element. The X509IssuerSerial element contains the X509IssuerName and X509SerialNumber elements. (M24, M25, M27, M28, M30, M126, M42, M47, M51, M56)

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8.8.2.2. Test Case Requirement - Verification of backwards compatibility with minor pre-standard version of schema

TPId: TCR-13		
Requirement Purpose: To verify that the ReceivedPedigree and its content comply with the specification for backwards compatibility between minor versions of the schema using the pre-standard version of the schema. The test will verify the ability to receive a pedigree from a manufacturer with a pedigree serial number that does not have the URN namespace prefix using the Interim Standard and then update the pedigree with a serial number that does have a URN namespace prefix using the ratified standard. **Requirement Tested:** 159, M161,162		
IUT role: Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create a pedigree. • Expiration date is a required element. • Manufacturer pedigree is for non-serialized items. • Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.		
Step	**Step description**	**Expected results**
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. 3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in UUID format without the URN namespace prefix and the pedigree schema minor version in the version element. The minor version will be

		for the Interim Standard. (M161, 159, 162) 4. initialPedigree, itemInfo, transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. 5. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer.
2	IUT applies receiving information to pedigree and digitally signs pedigree.	Verify that the pedigree is updated with the receiving information for the full quantity receipt and that it is digitally signed. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace, and wrapping the new receivedPedigree and Signature elements. 2. receivedPedigree element (inside the Pedigree element) with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. 3. documentInfo element (inside the receivedPedigree element) containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. The minor version will be for the ratified version of the schema. (M161, 159, 162)

		4. Complete Pedigree element for the pedigree that was received from the manufacturer in step 1 (inside the receivedPedigree element). 5. receivingInfo element (inside the receivedPedigree element) containing the dateReceived and itemInfo elements. The itemInfo element contains the lot, expirationDate and quantity elements. 6. signatureInfo element (inside the receivedPedigree element) containing the signerInfo, signatureDate and signatureMeaning elements. The signerInfo contains the name and title elements. 7. Signature element (inside the Pedigree element and signing the receivedPedigree element) containing SignedInfo, SignatureValue, and KeyInfo elements. The SignedInfo element contains the CanonicalizationMethod, SignatureMethod, and Reference elements. The Reference element contains the Transforms, DigestMethod and DigestValue elements. The KeyInfo element contains the X509Data element, with an X509IssuerSerial and X509Certificate element. The X509IssuerSerial element contains the X509IssuerName and X509SerialNumber elements.

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8.9. Test Scenario – 9: Wholesaler receives signed pedigree from manufacturer and certifies for receipt of partial quantity

8.9.1. Test Data

Data Elements	Data Value
Product Info	
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC542 or NDC442 or NDC541 or NDC532
Product Code Value	“3333-0014-06”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“1000”
Item Info	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	4
Item Serial Number	“00012345”
Item Serial Number	“00012346”
Item Serial Number	“00012347”
Item Serial Number	“00012348”
Sender Info/ Business Address	
Business Name	“Acme Laboratories”
Street Address1	“321 Main Street”
City	“Anytown”
State	“NJ”
Postal Code	“01900”
Country	“USA”

Data Elements	Data Value
License Number	“NJ3333”
State	“NJ”
Agency	“DOH”
Sender Contact Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Sender Signature Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Signature Meaning	Certified
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	purchase order number

Data Elements	Data Value
Transaction Type	Sale
Transaction Date	08/21/2006
Receiving Info	
Date Received	8/22/2006
Lot	“1234-A”
Quantity	1
Item Serial Number	“00012345”
Recipient Signature Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Signature Meaning	Received and Authenticated
Pedigree Version Info for Default Test Case	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20061220
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for wholesaler received pedigree	20061220
Pedigree Version Info for Forwards Compatibility Test Case	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20061220
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for wholesaler received pedigree	20060418 or 20060331

8.9.2. Test Cases

8.9.2.1. Test Case Requirement - Verification of a pedigree received from manufacturer for serialized items and certified for receipt of partial quantity

TPId: TCR-14		
Requirement Purpose: To verify that the ReceivedPedigree and its content comply with the specification when the electronic pedigree for serialized product is received by a wholesaler from a manufacturer, updated with receipt for a partial quantity, and digitally signed. **Requirement Tested:** M82, M86, M88, M90		
IUT role: Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create a pedigree. • Expiration date is a required element. • Manufacturer pedigree is for serialized items. • Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.		
Step	**Step description**	**Expected results**
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. 3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in

		the version element. 4. initialPedigree, itemInfo, transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. 5. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer.
2	IUT applies partial receiving information to pedigree and digitally signs pedigree.	Verify that the pedigree is updated with the receiving information for the partial quantity receipt and that it is digitally signed. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace, and wrapping the new receivedPedigree and Signature elements. 2. receivedPedigree element (inside the Pedigree element) with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. 3. documentInfo element (inside the receivedPedigree element) containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. 4. Complete Pedigree element for the pedigree that was received from the

		manufacturer in step 1 (inside the receivedPedigree element 5. receivingInfo element (inside the receivedPedigree element) containing the dateReceived and itemInfo elements. The itemInfo element contains the lot, expirationDate, quantity, and itemSerialNumber elements for the partial quantity received. (M82, M86, M88, M90) 6. signatureInfo element (inside the receivedPedigree element) containing the signerInfo, signatureDate and signatureMeaning elements. The signerInfo contains the name and title elements. 7. Signature element (inside the Pedigree element and signing the receivedPedigree element) containing SignedInfo, SignatureValue, and KeyInfo elements. The SignedInfo element contains the CanonicalizationMethod, SignatureMethod, and Reference elements. The Reference element contains the Transforms, DigestMethod and DigestValue elements. The KeyInfo element contains the X509Data element, with an X509IssuerSerial and X509Certificate element. The X509IssuerSerial element contains the X509IssuerName and X509SerialNumber elements.

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8.9.2.2. Test Case Requirement - Verification of forwards compatibility with minor version of schema

TPId: TCR-15		
Requirement Purpose: To verify that the ReceivedPedigree and its content comply with the specification for forwards compatibility between minor versions of the schema using the pre-standard version of the schema. The test will verify the ability to receive a pedigree from a manufacturer in the standard version and then send out a pedigree in the interim version of the schema. **Requirement Tested:** M164 ***Note: It is unclear if requirement M164 is a future requirement for when a new minor version of the schema becomes available. The ability to produce a pedigree in the Interim Standard has never been an EPCglobal requirement, however the use of the Interim Standard could help satisfy this test. This test may be deferred to the future if it is deemed inappropriate to use the Interim Standard in a forward compatibility fashion.		
IUT role: Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create a pedigree. • Expiration date is a required element. • Manufacturer pedigree is for serialized items. • Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.		
Step	**Step description**	**Expected results**
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. The minor version will be for the Interim version of the pedigree schema.

		3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in the version element. The minor version will be for ratified version of the schema. (M164) 4. initialPedigree, itemInfo, transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. 5. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer.
2	IUT applies partial receiving information to pedigree and digitally signs pedigree.	Verify that the pedigree is updated with the receiving information for the partial quantity receipt and that it is digitally signed. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace, and wrapping the new receivedPedigree and Signature elements. 2. receivedPedigree element (inside the Pedigree element) with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. 3. documentInfo element (inside the receivedPedigree element)

		containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. The minor version will be for the Interim Standard. (M164) 4. Complete Pedigree element for the pedigree that was received from the manufacturer in step 1 (inside the receivedPedigree element). 5. receivingInfo element (inside the receivedPedigree element) containing the dateReceived and itemInfo elements. The itemInfo element contains the lot, expirationDate, quantity, and itemSerialNumber elements for the partial quantity received. 6. signatureInfo element (inside the receivedPedigree element) containing the signerInfo, signatureDate and signatureMeaning elements. The signerInfo contains the name and title elements. 7. Signature element (inside the Pedigree element and signing the receivedPedigree element) containing SignedInfo, SignatureValue, and KeyInfo elements. The SignedInfo element contains the CanonicalizationMethod, SignatureMethod, and Reference elements. The Reference element contains the Transforms, DigestMethod and DigestValue elements. The KeyInfo element contains the X509Data element, with an X509IssuerSerial and X509Certificate element. The

		X509IssuerSerial element contains the X509IssuerName and X509SerialNumber elements.

326 ## 8.10. Test Scenario – 10: Wholesaler receives signed
327 pedigree from manufacturer and updates with receipt
328 information without applying a signature
329

330 ### 8.10.1. Test Data
331

Data Elements	**Data Value**
Extension Data in Document Info	
Extension data for date the document id was issued	Element name=”documentDate”, type=”xs:date” Value=2006-08-21
Product Info	
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC542 or NDC442 or NDC541 or NDC532
Product Code Value	“3333-0014-06”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“1000”
Item Info for Lot A	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	4
Item Serial Number	“00012345”
Item Serial Number	“00012346”
Item Serial Number	“00012347”

Data Elements	Data Value
Item Serial Number	“00012348”
Item Info for Lot B	
Lot	“1234-B”
Expiration Date	06/01/2016
Quantity	4
Item Serial Number	“00912345”
Item Serial Number	“00912346”
Item Serial Number	“00912347”
Item Serial Number	“00912348”
Sender Info/ Business Address	
Business Name	“Acme Laboratories”
Street Address1	“321 Main Street”
City	“Anytown”
State	“NJ”
Postal Code	“01900”
Country	“USA”
License Number	“NJ3333”
State	“NJ”
Agency	“DOH”
Sender Contact Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Sender Signature Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”

Data Elements	Data Value
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Signature Meaning	Certified
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	purchase order number
Transaction Type	Sale
Transaction Date	08/21/2006
Alternate Transaction Identifier	03333
Alternate Transaction Identifier Type	Invoice number
Receiving Info	
Date Received	8/22/2006
Lot	“1234-A”
Quantity	4
Item Serial Number	“00012345”
Item Serial Number	“00012346”
Item Serial Number	“00012347”
Item Serial Number	“00012348”
Receiving Info for Lot B	

Data Elements	Data Value
Lot	“1234-B”
Quantity	4
Item Serial Number	“00912345”
Item Serial Number	“00912346”
Item Serial Number	“00912347”
Item Serial Number	“00912348”
Pedigree Version Info for Default Test Case	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20061220
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for wholesaler received pedigree	20061220

8.10.2. Test Cases

8.10.2.1. Test Case Requirement - Verification of a pedigree received from manufacturer for serialized items and updated with receipt of full quantity without applying a signature.

TPId: TCR-16
Requirement Purpose: To verify that the UnsignedReceivedPedigree and its content comply with the specification when the electronic pedigree for serialized product from multiple lots is received by a wholesaler from a manufacturer, updated for receipt of the full quantity, without applying a signature. The manufacturer pedigree contains extension data. **Requirement Tested:** M23, M24, M25, M26, M27, M28, M42, M74, M75, M82, M88, M90, M104, M105, M121, M122
IUT role: Wholesaler.

Pre-test conditions:

- IUT is running and operational.
- Provide test data to IUT to create a pedigree.
- Expiration date is a required element.
- Manufacturer pedigree is for serialized product from multiple lots and contains extension data.
- Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.

Step	Step description	Expected results
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. (M23) 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. (M24, M25) 3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in the version element. (M24, M25) 4. Extension data in the documentInfo element using the BaseExtensibleType containing the documentDate. (M121, M122) 5. initialPedigree, itemInfo, transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. The itemInfo element contains two itemInfo elements containing the lot, expirationDate, quantity, and itemSerialNumber elements for the

		items in the two lots received. (M24, M25) 6. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer. (M24, M25)
2	IUT applies receiving information to pedigree with no signature.	Verify that the pedigree is updated with the receiving information for the full quantity receipt without applying a signature. Verify that the pedigree contains the following items correctly: 1. unsignedReceivedPedigree element with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. (M24, M25, M26, M27, M28, M74, M75) 2. documentInfo element (inside the unsignedReceivedPedigree element) containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. (M24, M25, M27, M42) 3. Complete Pedigree element for the pedigree that was received from the manufacturer in step 1 (inside the unsignedReceivedPedigree element). (M23, M24, M25, M27) 4. receivingInfo element (inside the unsignedReceivedPedigree element) containing the dateReceived and itemInfo elements. Two itemInfo elements containing the lot, expirationDate, quantity, and

		itemSerialNumber elements for the items in the two lots received. (M24, M25, M26, M27, M42, M82, M88, M90, M104, M105)

338

339 #### 8.10.2.2. Test Case Requirement - Verification of a
340 pedigree received from manufacturer with an alternate
341 transaction identifier for serialized items with receipt of full
342 quantity without applying a signature.

TPId: TCR-17		
Requirement Purpose: To verify that the IUT receives a pedigree with an alternate transaction identifier and that the UnsignedReceivedPedigree and its content comply with the specification when the electronic pedigree for serialized product from is received by a wholesaler from a manufacturer, updated for receipt of the full quantity, without applying a signature. **Requirement Tested:** M30, M93, M94		
IUT role: Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create a pedigree. • Expiration date is a required element. • Manufacturer pedigree is for serialized product of Lot A and has an alternate transaction identifier. • Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.		
Step	**Step description**	**Expected results**
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. The minor version will be for the Interim version of the pedigree schema.

		3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in the version element. 4. initialPedigree, itemInfo, transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. The transactionInfo element contains an optional altTransactionIdentifier element. The transactionDate element applies to the primary transactionInfo element. (M30, M93, M94) 5. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer.
2	IUT applies receiving information to pedigree with no signature.	Verify that the pedigree is updated with the receiving information for the full quantity receipt without applying a signature. Verify that pedigree contains the following items correctly: 1. unsignedReceivedPedigree element with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. 2. documentInfo element (inside the unsignedReceivedPedigree element) containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element.

		3. Complete Pedigree element for the pedigree that was received from the manufacturer in step 1 (inside the unsignedReceivedPedigree element). 4. receivingInfo element (inside the unsignedReceivedPedigree element) containing the dateReceived and itemInfo elements.

8.11. Test Scenario – 11: Wholesaler updates pedigree with receipt information on behalf of customer for a return transaction without applying a signature

8.11.1. Test Data

Data Elements	**Data Value**
Product Info	
Drug Name	"Product A"
Manufacturer	"Acme Laboratories"
Product Code Type	NDC542 or NDC442 or NDC541 or NDC532
Product Code Value	"3333-0014-06"
Dosage Form	"TABLETS"
Strength	"60 mg"
Container Size	"1000"
Item Info	
Lot	"1234-A"
Expiration Date	05/01/2016
Quantity	4
Sender Info/ Business Address	
Business Name	"Acme Laboratories"
Street Address1	"321 Main Street"
City	"Anytown"

Data Elements	Data Value
State	“NJ”
Postal Code	“01900”
Country	“USA”
License Number	“NJ3333”
State	“NJ”
Agency	“DOH”
Sender Contact Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	PurchaseOrderNumber
Transaction Type	Sale
Transaction Date	08/21/2006
Receiving Info	
Date Received	8/22/2006

Data Elements	Data Value
Lot	“1234-A”
Quantity	4
Pedigree Version Info for Default Test Case	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20061220
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for wholesaler received pedigree	20061220

347

348 The following table contains sample test data for wholesaler to use while selling product
349 bought from Acme lab to retailer.

350

Data Elements	Value
Sender Info/ Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL4444”
State	“FL”
Agency	“DOH”
Sender Contact Info	
Name	“Mary J. Greene”
Title	“Manager”

Data Elements	Value
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Sender Signature Info	
Name	“Mary J. Greene”
Title	“Manager”
Telephone	“800-521-6010”
Email	“mjgreene@majorwholesales.com”
URL	“www.majorwholesales.com”
Signature Meaning	Certified
Recipient Info / Business Address	
Business Name	“Retail Pharmacy”
Street Address1	“7890 Grand Road”
City	“Sometown”
State	“FL”
Postal Code	“10101”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“01111”
Transaction Identifier Type	ShippingNumber
Transaction Type	Sale
Transaction Date	08/23/2006
Item Info for Items in Transaction	
Lot	“1234-A”
Expiration Date	05/01/2016
Quantity	1

351

352 The following table contains sample test data for wholesaler to use while updating the
353 pedigree with the return transaction from the retailer.

354

Data Elements	**Value**
Sender Info/ Business Address	
Business Name	“Retail Pharmacy”
Street Address1	“7890 Grand Road”
City	“Sometown”
State	“FL”
Postal Code	“10101”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Sender Contact Info	
Name	“Mark Jones”
Title	“Manager”
Telephone	“800-541-6632”
Email	“mjones@retailpharmacy.com”
URL	“www.retailpharmacy.com”
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL4444”
State	“FL”

Data Elements	Value
Agency	"DOH"
Transaction Identifier	
Identifier	"08888"
Transaction Identifier Type	ReturnAuthorizationNumber
Transaction Type	Return
Transaction Date	08/25/2006
Receiving Info for Return Transaction	
Date Received	8/25/2006
Lot	"1234-A"
Quantity	1

355

356

357 8.11.2. Test Cases

358 8.11.2.1. Verification of a pedigree updated by a 359 wholesaler on behalf of customer for a return transaction of 360 non-serialized items without applying a signature.

TPId: TCR-18		
Requirement Purpose: To verify that the UnsignedReceivedPedigree and its content comply with the specification when the electronic pedigree for non-serialized product is created by the wholesaler and provided to the customer, and then updated with the customer return transaction without applying a signature. **Requirement Tested:** M32, M33, M76		
IUT role: Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create a pedigree. • Expiration date is a required element. • Wholesaler pedigree is for non-serialized product. • Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.		
Step	**Step description**	**Expected results**

1	IUT creates a pedigree.	Verify that a pedigree is created by IUT. Verify that the pedigree contains the following items correctly: 1. initialPedigree element containing the serialNumber in URN UUID format, productInfo, itemInfo, transactionInfo, and receivingInfo elements with information from the sales transaction from the manufacturer to the wholesaler. The itemInfo element contains the lot, expirationDate and quantity elements for the non-serialized items sold from the manufacturer to the wholesaler.
2	IUT applies sales transaction from wholesaler to pharmacy with signature and provides pedigree to pharmacy.	Verify that the pedigree is updated with the transaction information and signed. Verify that the signed shipped pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. 3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in the version element. 4. initialPedigree (created in step 1) and the itemInfo, transactionInfo and signatureInfo elements for the new sales transaction (inside the shippedPedigree element).

		5. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the wholesaler.
3	IUT applies return information to pedigree with no signature.	Verify that the pedigree is updated with the return information for the full quantity of the return without applying a signature. Verify that the pedigree contains the following items correctly: 1. unsignedReceivedPedigree element with a unique id attribute, and wrapping the complete Pedigree that was originally shipped to the customer and adding information about the return. 2. documentInfo element (inside the unsignedReceivedPedigree element) containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. 3. Complete Pedigree element for the pedigree that was originally shipped to the customer from step 2 (inside the unsignedReceivedPedigree element). 4. transactionInfo element (inside the unsignedReceivedPedigree element) containing the senderInfo, recipientInfo, transactionIdentifier, transactionType and transactionDate. The senderInfo contains information about the customer making the return. The recipientInfo contains information about the wholesaler accepting the return. The

		transactionIdentifier contains the identifier and identifierType of the business document associated with the return transaction. The transactionType identifies the return transaction. The transactionDate contains the date of the return transaction (M32, M33, M76) 5. receivingInfo element (inside the unsignedReceivedPedigree element) containing the dateReceived and itemInfo elements. The itemInfo element contains the lot, expirationDate and quantity elements for the items returned.

8.12. Test Scenario – 12: Backwards compatibility between major versions of schema.

8.12.1. Test Data

Data Elements	**Data Value**
Product Info	
Drug Name	“Product A”
Manufacturer	“Acme Laboratories”
Product Code Type	NDC542 or NDC442 or NDC541 or NDC532
Product Code Value	“3333-0014-06”
Dosage Form	“TABLETS”
Strength	“60 mg”
Container Size	“1000”
Item Info for Lot A	
Lot	“1234-A”

Data Elements	Data Value
Expiration Date	05/01/2016
Quantity	4
Item Serial Number	“00012345”
Item Serial Number	“00012346”
Item Serial Number	“00012347”
Item Serial Number	“00012348”
Item Info for Lot B	
Lot	“1234-B”
Expiration Date	06/01/2016
Quantity	4
Item Serial Number	“00912345”
Item Serial Number	“00912346”
Item Serial Number	“00912347”
Item Serial Number	“00912348”
Sender Info/ Business Address	
Business Name	“Acme Laboratories”
Street Address1	“321 Main Street”
City	“Anytown”
State	“NJ”
Postal Code	“01900”
Country	“USA”
License Number	“NJ3333”
State	“NJ”
Agency	“DOH”
Sender Contact Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”

Data Elements	Data Value
URL	“www.acmelabs.com”
Sender Signature Info	
Name	“John Brown”
Title	“Manager”
Telephone	“888-231-1000”
Email	“johnbrown@acmelabs.com”
URL	“www.acmelabs.com”
Signature Meaning	Certified
Recipient Info / Business Address	
Business Name	“Major Wholesales”
Street Address1	“456 Town Road”
City	“Major City”
State	“FL”
Postal Code	“10100”
Country	“USA”
License Number	“FL5555”
State	“FL”
Agency	“DOH”
Transaction Identifier	
Identifier	“02222”
Transaction Identifier Type	purchase order number
Transaction Type	Sale
Transaction Date	08/21/2006
Alternate Transaction Identifier	03333
Alternate Transaction Identifier Type	Invoice number
Receiving Info	
Date Received	8/22/2006
Lot	“1234-A”
Quantity	4

Data Elements	Data Value
Item Serial Number	“00012345”
Item Serial Number	“00012346”
Item Serial Number	“00012347”
Item Serial Number	“00012348”
Receiving Info for Lot B	
Lot	“1234-B”
Quantity	4
Item Serial Number	“00912345”
Item Serial Number	“00912346”
Item Serial Number	“00912347”
Item Serial Number	“00912348”
Pedigree Version Info for Default Test Case	
Major version for manufacturer shipped pedigree	urn:epcGlobal:Pedigree:xsd:1
Minor version for manufacturer shipped pedigree	20061220
Major version for wholesaler received pedigree	urn:epcGlobal:Pedigree:xsd:2
Minor version for wholesaler received pedigree	YYYYMMDD

8.12.2. Test Cases

8.12.2.1. Verification of a pedigree received from manufacturer with an older major version of the schema and updating of pedigree by wholesaler with a newer major version of the schema.

TPId: TCR-19
Requirement Purpose: To verify that the ReceivedPedigree and its content comply with the specification when the electronic pedigree for serialized product is received by a wholesaler from a manufacturer using an older major version of the schema, and

updated with receipt using a newer major version of the schema, and digitally signed.

Requirement Tested: M163

*** Note: Requirement M163 is a future requirement for when a new major version of the schema becomes available.

*** Note that Requirements M165, M166 and M167 are instructional requirements for how EPCglobal and trading partners should move forward with releasing future versions of schema and are not requirements that can be tested.

IUT role: Wholesaler.

Pre-test conditions:

- IUT is running and operational.
- Provide test data to IUT to create a pedigree.
- Expiration date is a required element.
- Test data should contain enough information necessary to create a complete shipped pedigree along with the receiving information to represent a sale of drugs from manufacturer to wholesaler.

Step	Step description	Expected results
1	IUT receives a pedigree.	Verify that a pedigree is received from IUT. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace. The major version is version 1. (M163) 2. shippedPedigree element (inside the Pedigree element) with a unique id attribute. 3. documentInfo element (inside the shippedPedigree element) containing the unique pedigree serialNumber in URN UUID format and the pedigree schema minor version in the version element. 4. initialPedigree, itemInfo,

		transactionInfo, signatureInfo (inside the shippedPedigree element) provided by the manufacturer. 5. Signature element (inside the Pedigree element and signing the shippedPedigree element) containing the digital signature provided by the manufacturer.
2	IUT applies receiving information to pedigree and digitally signs pedigree.	Verify that the pedigree is updated with the receiving information and that it is digitally signed. Verify that the pedigree contains the following items correctly: 1. Pedigree element with the pedigree major version specified in the namespace, and wrapping the new receivedPedigree and Signature elements. The major version of the pedigree is version 2. (M163) 2. receivedPedigree element (inside the Pedigree element) with a unique id attribute, and wrapping the complete Pedigree that was received and adding information about the receipt. 3. documentInfo element (inside the receivedPedigree element) containing the unique pedigree serial number in the URN UUID format in the serialNumber element and the pedigree schema minor version in the version element. 4. Complete Pedigree element for the pedigree that was received from the manufacturer in step 1 (inside the receivedPedigree element

		5. receivingInfo element (inside the receivedPedigree element) containing the dateReceived and itemInfo elements. The itemInfo element contains the lot, expirationDate, quantity, and itemSerialNumber elements for the partial quantity received. 6. signatureInfo element (inside the receivedPedigree element) containing the signerInfo, signatureDate and signatureMeaning elements. The signerInfo contains the name and title elements. 7. Signature element (inside the Pedigree element and signing the receivedPedigree element) containing SignedInfo, SignatureValue, and KeyInfo elements. The SignedInfo element contains the CanonicalizationMethod, SignatureMethod, and Reference elements. The Reference element contains the Transforms, DigestMethod and DigestValue elements. The KeyInfo element contains the X509Data element, with an X509IssuerSerial and X509Certificate element. The X509IssuerSerial element contains the X509IssuerName and X509SerialNumber elements.

8.13. Test Scenario – 13: Mapping for a Pedigree Referring to Products in a Single Serialized Case

8.13.1. Test Data

Data Elements	Data Value
Version	20061122
Serial Number	95e0f2e1-c0a8-0172-704f-cc1c308e8610
Date	2006-12-18
Source Routing Code	MF1001
Destination Routing Code	WL1002
Container Code	ABC145212
Shipment Handle	254124511
Ship From Location	ABC451245251
Ship To Location	XYZ78945612454
Pedigree Serial Number	1f77db96-c0a8-01cc-03b8-03b8536ab06a
Item serial number	12452122

8.13.2. Test Cases

8.13.2.1. 8.1.2.1 Verification of Envelope elements and its content for a Pedigree Referring to Products in a Single Serialized Case

TPId: TCR-20		
Requirement Purpose: To verify that the Envelope and its content comply with the specification when the electronic pedigree envelope for a pedigree referring to products in a single serialized case **Requirement Tested:** M127-M139, M153,M155		
IUT role: Manufacturer / Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create an envelope. • Test data should contain enough information necessary to create a complete pedigree envelope.		
Step	**Step description**	**Expected results**

1	Provide input data to IUT in supported format. Input data should contain the data required for this test.	Verify that an envelope is received from IUT. Verify that the received envelope contains the following items correctly: 1. PedigreeEnvelope that contains the desired version, serial number, date, source routing code, destination routing code, container and pedigree. 2. Container (inside the PedigreeEnvelope) that contains desired container code, shipment hanle, ship from location code, ship to location code and pedigree handle. 3. PedigreeHandle (inside container) that contains desired serial number, item serial number

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8.14. Test Scenario – 14: Mapping for a Pedigree Referring to Products in a Multi Serialized Case

8.14.1. Test Data

Data Elements	Data Value
Version	20061122
Serial Number	95e0f2e1-c0a8-0172-704f-cc1c308e8610
Date	2006-12-18
Source Routing Code	MF1001
Destination Routing Code	WL1002
Container Code	ABC145212
Shipment Handle	254124511
Ship From Location	ABC451245251
Ship To Location	XYZ78945612454
Pedigree Serial Number	1f77db96-c0a8-01cc-03b8-03b8536ab06a
Item serial number	12452122
Item serial number	12452123
Item serial number	12452124

8.14.2. Test Cases

8.14.2.1. 8.2.2.1 Verification of Envelope elements and its content for a Pedigree Referring to Products in a Multi Serialized Case

TPId: TCR-21

Requirement Purpose: To verify that the Envelope and its content comply with the specification when the electronic pedigree envelope for a pedigree referring to products in a multi serialized case **Requirement Tested:** M127-M139 ,M142, M153,M155		
IUT role: Manufacturer / Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create an envelope. • Test data should contain enough information necessary to create a complete pedigree envelope.		
Step	**Step description**	**Expected results**
1	Provide input data to IUT in supported format. Input data should contain the data required for this test.	Verify that an envelope is received from IUT. Verify that the received envelope contains the following items correctly: 1. PedigreeEnvelope that contains the desired version, serial number, date, source routing code, destination routing code, container and pedigree. 2. Container (inside the PedigreeEnvelope) that contains desired container code, shipment handle, ship from location code, ship to location code and pedigree handle. 3. PedigreeHandle (inside container) that contains desired serial number and list of item serial numbers

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8.15. Test Scenario – 15: No Mapping for a Pedigree Referring to Products Case

8.15.1. Test Data

Data Elements	Data Value
Version	20061122
Serial Number	95e0f2e1-c0a8-0172-704f-cc1c308e8610
Date	2006-12-18
Source Routing Code	MF1001
Destination Routing Code	WL1002

8.15.2. Test Cases

8.15.2.1. 8.3.2.1 Verification of Envelope elements and its content for no mapping for a Pedigree Referring to Products Case

TPId: TCR-22		
Requirement Purpose: To verify that the Envelope and its content comply with the specification when the electronic pedigree envelope for a no mapping for a pedigree referring to products. **Requirement Tested:** M127,M128 M129,M130, M153,M155		
IUT role: Manufacturer / Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create an envelope. • Test data should contain enough information necessary to create a complete pedigree envelope.		
Step	**Step description**	**Expected results**

1	Provide input data to IUT in supported format. Input data should contain the data required for this test.	Verify that an envelope is received from IUT. Verify that the received envelope contains the following items correctly: 1. PedigreeEnvelope that contains the desired version, serial number, date, source routing code, destination routing code and pedigree.

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414 ## 8.16. Test Scenario – 16: Mapping for a Pedigree Referring to
415 Products in a Non Serialized Case

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417 ### 8.16.1. Test Data

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Data Elements	Data Value
Version	20061122
Serial Number	95e0f2e1-c0a8-0172-704f-cc1c308e8610
Date	2006-12-18
Source Routing Code	MF1001
Destination Routing Code	WL1002
Container Code	ABC145212
Shipment Handle	254124511
Ship From Location	ABC451245251
Ship To Location	XYZ78945612454
Pedigree Serial Number	1f77db96-c0a8-01cc-03b8-03b8536ab06a
Product Code	3243-3433-34
Lot	ASW23
Quantity	3

8.16.2. Test Cases

8.16.2.1. 8.4.2.1 Verification of Envelope elements and its content for a Pedigree Referring to Products in a Non Serialized Case

TPId: TCR-23		
Requirement Purpose: To verify that the Envelope and its content comply with the specification when the electronic pedigree envelope for a pedigree referring to products in a non serialized case **Requirement Tested:** M127-M147 , M153,M155		
IUT role: Manufacturer / Wholesaler.		
Pre-test conditions: • IUT is running and operational. • Provide test data to IUT to create an envelope. • Test data should contain enough information necessary to create a complete pedigree envelope.		
Step	**Step description**	**Expected results**
1	Provide input data to IUT in supported format. Input data should contain the data required for this test.	Verify that a envelope is received from IUT. Verify that the received envelope contains the following items correctly: 2. PedigreeEnvelope that contains the desired version, serial number, date, source routing code, destination routing code, container and pedigree. 4. Container (inside the PedigreeEnvelope) that contains desired container code, shipment handle, ship from location code, ship to location code and pedigree handle. 5. PedigreeHandle (inside container) that contains desired serial number, product code, lot and quantity.

9. References