PDG Blueprint Chapter 5

Trace Design Requirements and Acceptance Criteria

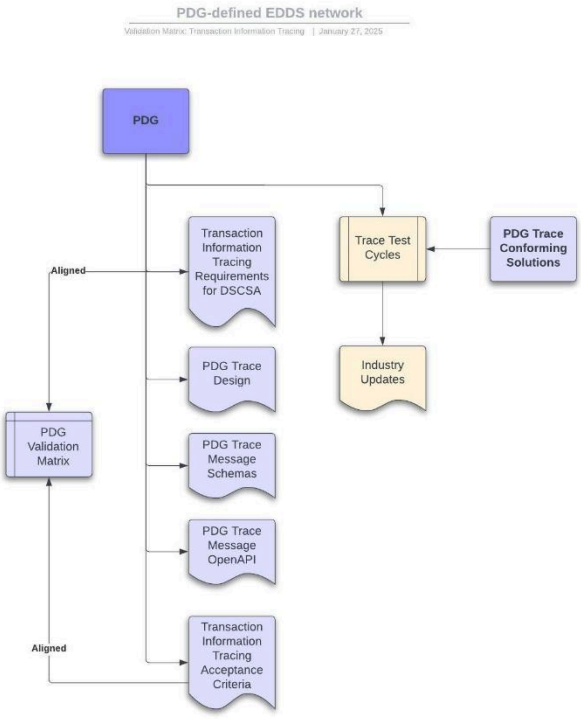

Figure 1 - Alignment between PDG Requirements, Acceptance Criteria and Tracing Requirements

PDG Blueprint Chapter 5

Trace Design Requirements and Acceptance Criteria

Contents

Categories

1. Connectivity
2. Authentication/Authorization
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REQ18 - Sharing Trace Endpoints

Trading partners (ATPs and ATP Equivalents) SHALL provide their Trace Endpoint to their customer and supplier trading partners.

Category

Connectivity

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 001

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. The system must hold or be able to access a valid trace endpoint for each entity to which TI/TS records have been received or provided.
   b. The system must provide a valid trace endpoint to each entity to which TI/TS records have been received or provided.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. An ATP or ATP Equivalent has exchanged TI/TS records with a Supplier or Customer.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. A Trace Endpoint is available for each entity to which TI/TS records have been received or provided.
   b. A process is in place to provide a valid trace endpoint to each entity to which TI/TS records have been received or provided.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. **Pass Criteria:**
      1. A Trace Endpoint is available for each entity to which TI/TS records have been received or provided.
      2. A process is in place to provide a valid trace endpoint to each entity to which TI/TS records have been received or provided.
   b. **Fail Criteria:**
      1. A Trace Endpoint is unavailable for each entity to which TI/TS records have been received or provided.

2. A process is not in place to provide a valid trace endpoint to each entity to which TI/TS records have been received or provided.

5. **Expected Successful Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is met.

- **TI Requests** can be sent to the proper Trace Endpoint.
    - TI Requests will result in TI Response conformant with the TI Response schema (or response outside the electronic network).
- **TI Responses** can include the proper Trace Endpoints of trading partners documented in TI[1].
    - TI Responses include the providing or receiving TI record's Connectivity Information where TI Requests can be sent (tiRequestConnectivityInformation in the TI Response schema).

6. **Expected Failure Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is unmet.

- **TI Requesters:**
    a. TI Requests cannot be sent to the proper Trace Endpoint.
        - TI Requesters are forced to use existing contact information for the customer or supplier (to either request Trace endpoint information or route a TI Request).
- **TI Responders[2]:**
    a. TI Responses cannot include the proper Trace Endpoints of trading partners documented in TI.
    b. Responders may include a general contact endpoint (email address).

[1] In the case of a dropship transaction, the Responding party may only be able to give a general email address of some parties.
[2] TI Responses include Trace Connectivity Information for each party in the transaction.

REQ19 - Maintaining Trace Endpoints

Should a company's Trace Endpoint change, trading partners (ATPs and ATP Equivalents) SHALL provide their updated Trace Endpoint to their customer and supplier trading partners.

Category

Connectivity

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 002

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   c. The system must be able to update or access a valid trace endpoint for each entity to which TI/TS records have been received or provided.
   d. The system must provide updated trace endpoints to each entity to which TI/TS records have been received or provided.

2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.

   a. An ATP or ATP Equivalent has updated its Trace Endpoint.

3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   i. A valid Trace Endpoint is available for each entity to which TI/TS records have been received or provided.
   ii. The system uses the updated trace endpoint in new TI Responses.
   iii. A process is in place to provide an updated trace endpoint to each entity to which TI/TS records have been received or provided.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. **Pass Criteria:**
      1. A valid Trace Endpoint is available for each entity to which TI/TS records have been received or provided.
      2. A process is in place to provide updated trace endpoint to each entity to which TI/TS records have been received or provided.

   ii. **Fail Criteria:**

1. A valid Trace Endpoint is unavailable for entities to which TI/TS records have been received or provided.
2. A process is not in place to provide a valid trace endpoint to each entity to which TI/TS records have been received or provided.

5. **Expected Successful Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is met.

- **TI Requests** can be sent to the proper Trace Endpoint.
  - TI Requests will result in TI Response conformant with the TI Response schema (or response outside the electronic network).
- **TI Responses** can include the proper Trace Endpoints of trading partners documented in TI[3].
  - TI Responses include the providing or receiving TI record's Connectivity Information where TI Requests can be sent (tiRequestConnectivityInformation in the TI Response schema).

6. **Expected Failure Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is unmet.

- **TI Requesters:**
  a. TI Requests cannot be sent to the proper Trace Endpoint.
    - TI Requesters are forced to use existing contact information for the customer or supplier (to either request Trace endpoint information or route a TI Request).
- **TI Responders[4]:**
  a. TI Responses cannot include the proper Trace Endpoints of trading partners documented in TI.
  b. Responders may include a general contact endpoint (email address).

7. **Considerations:**
Clearly state information that may be helpful for proper implementation or operation.
Sharing Trace Endpoints in Dropship transactions:
   c. Manufacturer may share new endpoint with dispenser (via portal)
   d. Wholesalers may share the Manufacturer's new endpoint with the Dispenser based on Drop Ship order knowledge.

[3] In the case of a dropship transaction, the Responding party may only be able to give a general email address of some parties.
[4] TI Responses include Trace Connectivity Information for each party in the transaction.

REQ20 - Records Retention

Trading Partners (or their Solutions) SHALL retain Trace Request and Response records for 6 years after a Suspect Product Investigation or Illegitimate Product investigation.

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 003

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. Audit records are available for TI Requests and TI Responses.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. A request to view TI Request and TI Response records for a product transacted up to 6 years after a known Suspect or Illegitimate Product Investigation.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   i. TI Request and TI Response audit records are accessible for interactions where TI Request investigationReasonAttestation = “Suspect Product Investigation”, “Illegitimate Product Investigation”, or “Recalled Product Investigation”.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a “pass” or “fail” for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      TI Request and TI Response audit records are accessible.
   b. Fail Criteria:
      i. Failure of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

- **Requests and Responses retention:** Trading Partner can access Requests and Responses (audit records) associated with the investigation.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. The system cannot provide TI Requests and TI Responses associated with an investigation.

REQ21 - Multiple TI Requests

A TI Request May include requests for one or more Product ID [22] / Serial Number pair.

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 004

Notes

[22] GTIN or NDC.

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   A TI Responding system can process a TI Request message containing multiple *tiRequests*.

2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02 (ATP, ATP-Authority, DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. The *tiRequestSet* includes multiple *tiRequests*.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. A valid TI Request is received containing multiple tiRequests.
   b. The Responding system processes all the tiRequests in the TI Request message.
   c. The Responding system returns a TI Response containing a tiRequestRespponses set for each tiRequests.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. The responding system can process each request in tiRequests.
   b. Fail Criteria:
      i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   TI Requests will result in TI Responses conforming to the TI Response schema (or response outside the electronic network) for each request in tiRequests.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   TI Responder is unable to process multiple TI Requests.
   i. **Unwarranted Error message** is returned (cannot process as received).
   ii. **Partial Response:** TI Responder replies to a subset of TI Requests and, no other communication, outside of the system, regarding the requests is received.
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   In practice, the TIResponse may include one responseMessage covering all the tiRequests, or a tiResponse or requestLineNumberMessage for each request in the tiRequests array.

REQ22 - Investigation types

A TI Request Must indicate a single investigation type (Suspect, Illegitimate or Recall), or compliance audit.

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 005

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be considered successfully fulfilled.
   a. TI Request includes a single investigationReasonAttestation of “Suspect Product Investigation”, “Illegitimate Product Investigation”, “Recalled Product Investigation”, or “Compliance Audit”
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools that will be used for testing.
   a. Execute TI Request schema validation (see REQ46 – Schema Failure Exceptions).
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Schema validation will fail:
      i. Multiple or missing or incorrect investigationReasonAttestation
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   a. Schema validation passes.
6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   a. TI Request schema validation failure.
   b. TI Response responseMessage includes “xx2 Request parameter error.”
7. **Considerations:**

Clearly state information that may be helpful for proper implementation or operation.

a.

REQ23 - Suspect Product Investigation TI Request only at Case or Package level.

Suspect Product Investigations SHALL only allow for package or case level requests.

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 006

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. A TI Request with investigationReasonAttestation = “Suspect Product Investigation” includes individual tiRequests for Product ID (GTIN or NDC) and SerialNumber pairs only.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. TI Request with investigationReasonAttestation = “Suspect Product Investigation”
   b. serialOrLotNumber of all tiRequests is a serial number (not a lot number).
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. Requesting Systems: Can not generate a TI Request where investigationReasonAttestation = “Suspect Product Investigation” and serialNumberOrLotNumber contains a Lot Number.
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

a. TI Requests will result in TI Responses conforming with the TI Response schema (or response outside the electronic network) for each tiRequest.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. Responding Systems: return a “xx2 Request parameter error” for each request in *tiRequests* where investigationReasonAttestation = “Suspect Product Investigation” and serialNumberOrLotNumber contains a Lot Number.

7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.

   a.

REQ24 - Illegitimate Product Investigation TI Request only at Case or Package level.

Illegitimate Product Investigations SHALL only allow for package or case level requests.

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 007

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. A TI Request with investigationReasonAttestation = “Illegitimate Product Investigation” includes individual tiRequests for Product ID (GTIN or NDC) and SerialNumber pairs only.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. TI Request with investigationReasonAttestation = “Illegitimate Product Investigation”
   b. serialOrLotNumber of all tiRequests is a serial number (not a lot number).
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. Requesting Systems: Can not generate a TI Request where investigationReasonAttestation = “Illegitimate Product Investigation” and serialNumberOrLotNumber contains a Lot Number.
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

b. TI Requests will result in TI Responses conforming with the TI Response schema (or response outside the electronic network) for each tiRequest.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. Responding Systems: return a “xx2 Request parameter error” for each request in *tiRequests* where investigationReasonAttestation = “Suspect Product Investigation” and serialNumberOrLotNumber contains a Lot Number.

7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.

   a.

REQ25 - DSCSA Authorities may only submit TI Request for Recalled product reason at lot, case or package level.

Recalled Product Investigations SHALL only be submitted from a DSCSA Authority AND allow for package or case level requests or Lot level requests.

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 008

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. A TI Request with investigationReasonAttestation = “Recalled Product Investigation” includes individual tiRequests for Product ID (GTIN or NDC) and SerialNumber pairs only, and
   b. The Request is from a DSCSA Authority.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02, and Requester is a DSCSA Authority
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. Requester is determined to be a DSCSA Authority
      i. Credential provided can be verified as a DSCSA Authority credential, or
      ii. Internal processes are used to identify the Requester and determine Requester is a DSCSA Authority
   b. TI Request with investigationReasonAttestation = “Recalled Product Investigation”
   c. serialOrLotNumber of all tiRequests is a serial number or lot number.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. Requester is determined to be a DSCSA Authority
      ii. TI Request with investigationReasonAttestation = “Recalled Product

Investigation”

iii. serialOrLotNumber of all tiRequests is a serial number or lot number.

b. Fail Criteria:

i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is met.

c. TI Requests will result in TI Responses conforming with the TI Response schema (or response outside the electronic network) for each tiRequest.

6. **Expected Failure Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is unmet.

a. Responding Systems: return a “xx2 Request parameter error” for each request in *tiRequests* where investigationReasonAttestation = “Suspect Product Investigation” and serialNumberOrLotNumber contains a Lot Number.

7. **Considerations:**
Clearly state information that may be helpful for proper implementation or operation.

a.

REQ26 - TI Request criteria.

A set of TI Requests SHALL only specify a GTIN/Serial Number pair, a NDC/Serial Number Pair, a GTIN/Lot Number pair (Recalls) or a NDC/Lot Number pair (Recalls).

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 009

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. The Responding system can respond to the request with an appropriate message.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. .
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   .
6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   a. .
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.

a. This Requirement is handled by passing a schema check and requirements 22 through 25 and Req46 – Schema Failure Exceptions

REQ27 - Use of "Response Pending".

Responders may need additional time for a particular Product ID / Serial Number request. If that is the case, a response of “Response Pending” is given and a Response is provided later. This does not relieve trading partners of turnaround time as specified in the DSCSA **(24 hrs)** or FDA Guidances.

Category

TI Response

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 009

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. When additional time to respond is needed, the Responding system can send a TI Response with the message “xx3 Response Delayed”.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
   c. Responder determines that additional time is needed to process the request(s).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   TI Response includes a responseMessage containing “xx3 Response Delayed”, or
   TI Response includes a requestLineNumberMessage containing “xx3 Response Delayed” (for each individual tiRequest being delayed)
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. TI Response is sent with responseMessage containing “xx3 Response Delayed”, or
      ii. TI Response includes a requestLineNumberMessage containing “xx3 Response Delayed” (for each individual tiRequest being delayed)
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

a. TI Response Message includes code xx3, Response Delayed, or
b. TI Response includes a requestLineNumberMessage containing “xx3 Response Delayed” (for each individual tiRequest being delayed)

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. A full TI Response is not sent within 24hrs.

7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.

   a.

REQ28 - TI Response follow-up responses.

If a response is given for a particular item, and you later need to correct or provide additional data, a replacement or additional response can be made.

Category

TI Response

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 010

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. The additional information is provided in a TI Response where the *tiRequestID* and *requestLineNumber* are the same as the original TI Response.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
   c. Updated information on a requested item becomes available.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   i. The TI Response includes the *tiRequestID* of the original TI Request.
   ii. If individual *tiRequests* were made, the *requestLineNumber*(s) in the TI Response correspond to the original *requestLineNumber*(s).
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. TI Response *tiRequestID* and *requestLineNumber*(s) correspond to previous TI Request information.
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

- TI Response *requestLineNumberMessage* indicates the *tiRequestID* and *requestLineNumber*(s) being replaced or supplemented.
- Include the original *tiResponseID* in the *responseMessage* and indicate (in the *responseMessage*) that this is a replacement of or supplemental to a previous TI Response.
- *tiResponseTimestamp* occurs later than the *tiResponseTimestamp* on the original TI Response.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   a. A response with the same *tiRequestID* and *requestLineNumber*(s) as a previous response with no indication that it is a replacement or supplemental response (Requester may assume the new Response supersedes the old, or not know how to interpret the new Response).
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   a.

REQ29 - Responding if no record is found.

Responders Shall return the “No TI Response” message if they do not have TI records for a particular request.

Category

TI Response

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 011

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. For legitimate requests, TI Response(s) are returned, noting that no TI records were found using “xx2 No TI found for the Request”.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
   c. No TI records are found in the Responder’s system for the Request(s).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. If Responder has no TI records for all requests in a TI Request,
      i. the Ti Response responseMessageDescription = “xx2 No TI found for the Request” or,
      ii. TI Response requestLineNumberMessage = “xx2 No TI found for the Request” for each individual request.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. the Ti Response responseMessageDescription = “xx2 No TI found for the Request” or,
      ii. TI Response requestLineNumberMessage = “xx2 No TI found for the Request” for each individual request.
   b. Fail Criteria:
      i. Failure Of Pass Criteria (ex: Responder does not provide a TI

Response).

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   No records for all requests in the request set:
   responseMessage includes:
   a. responseMessageCode of “xx2”
   b. responseMessageDescription of “No TI found for the Request”
   No records for an individual request in the request set:
   requestLineNumberMessage includes:
   a. requestResponseMessageCode of “xx2”
   b. requestResponseMessageDescription of “No TI found for the Request”.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   No TI Response is returned, or other exception code/message is received.
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   a.

REQ30 - Connectivity checks.

Trace solutions implementing the TI Request and TI Response (via OpenAPI, DIDcomm,etc.) shall implement a connectivity check.

Category

Connectivity

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 011

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. Maturity Level 3 systems can execute connectivity checks with other trace systems.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Maturity Level 3: Requesting system issues a connectivity check to the Responding system via API or DIDComm.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. Requester or Responder system exercises a connectivity check with an API or DIDComm Trace endpoint.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. Connectivity check is successful.
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   a. Connectivity check is successful.
6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   a. Connectivity check is unavailable, or

b. Connectivity check fails.

7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.

   a.

REQ31 - Acknowledging TI Requests sent by email.

If trading partners are using email to transport TI Requests and TI Responses, an acknowledgment of the TI Request or TI Response SHALL be sent to the requester or responder.

Category

TI Response

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 012

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. **Responders** send an [receipt] acknowledgment for TI Responses using the TI Response *contactInformation*.
   b. **Requesters** send an [receipt] acknowledgment for TI Responses using the TI Response *contactInformation*.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. **For Responders:**
      i. TI Request message is received via email.
      ii. Must satisfy Req02
      iii. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
   b. **For Requesters:**
      i. TI Response message is received via email.
      ii. Must satisfy Req02
      iii. TI Response passes schema validation (data format and mandatory element checks as per TI Response schema).
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. **For Responders:**
      i. Requester sends a valid TI Request to a Responder via email.
      ii. Requester receives an email acknowledgement.
   b. **For Requesters:**
      i. Responders sends a valid TI Response to a Requester via email.

ii. Responder receives an email acknowledgment

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      i. The system receiving a TI Request or TI Response sends an email acknowledgement.
   b. Fail Criteria:
      i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

   - **Responder:** TI Responding email system sends an email receipt acknowledgment of Request.
   - **Requester:** TI Requester email system sends an email receipt acknowledgment of Response.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   - **Responder:** TI Responding email system does not send an email receipt acknowledgment of Request.
   - **Requester:** TI Requester email system does not send an email receipt acknowledgment of Response.

7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.

   a. Requesters and Responders should send emails with “receipt requested”

REQ32 - Required data attributes for TI Requests and TI Responses.

TI Request and TI Response message formats shall conform to a standardized message structure based on PDG-defined EDDS network's JSON schemas for tracing.

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 5

Source ID

Trace-FR- 013

Acceptance Criteria (see REQ46 – Schema Failure Exceptions)

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   TI Requests and TI Responses pass schema checks.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. TI Request or TI Response is received.
   b. Schema checks are performed.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   i. TI Request JSON files are validated against the current TI Request schema.
   ii. TI Request JSON files are validated against the current TI Request schema.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. TI Request or TI Response passes schema checks.
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   TI Request or TI Response is processed.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   TI Request JSON fails schema check:
   - At TI Request set level:
     - TI Response ResponseMessageCode = "xx9"[5]
     - TI Response ResponseMessageDescription of "Request Schema Failure"
     - Or,
   - At TI Request line level:
     - TI Response includes requestResponseMessageCode of "xx9" (new)
     - requestResponseMessageDescription of "Request Schema Failure"

   TI Response JSON fails schema check[6]:
   a. Blueprint has no provision for TI Response error notification.
   b. Contact the TI Response party about the issue.
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   a.

[5] xx9 Request schema failure is a new exception to Chapter 5 (needs change request)
[6] Potential Change Request to Chapter 5: Chapter 5, Figure 5 shows error processing on the part of the Requester. Need a mechanism for Requester system to notify Responder system of errors with response (ex: schema validation, etc.). Also, may need a new error code/desc. (ex: x10 Response Schema Error).

REQ35 - Returned Product TI Responses

Each trading partner must provide TI when transferring ownership, however, buyers are not required to provide a TI record to the supplier they returned it to. The Buyer's TI data will reflect that the ownership of the case or package was transferred to them, however there will be no TI documenting the transfer back to the supplier. Likewise, the Supplier's TI records might reflect the product being transferred from them twice.

Category

TI Response

Source Document

PDG Blueprint Chapter 5

Source ID

Returned Product section

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. Trading Partner will respond with information they hold in their TI/TS.
   b. Trading Partners may use the requestLineNumberMessage to also explain the returned product circumstances.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. TI Request passes data format and mandatory element checks as per TI Request schema.
   b. The TI Request concerns an item returned from the Buyer to the Seller.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   a. TI Responses will include information from the available TI/TS records of that Trading Partner.
   b. TI Response may also contain information about the return in the *requestLineNumberMessage*
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. Trading partner provides TI Response based on available TI/TS information and also may include information about the returned product(s) in the *requestLineNumberMessage*

b. Fail Criteria:
    i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is met.
Seller Response - Successful Outcome (TI Request received by the Seller):
    - Responder (Seller) may provide more than one outbound (1 for original Buyer and 1 for last Buyer) TI records in the response.
    - Responder may include a requestLineNumberMessage explaining that the item was returned.

Buyer (that returned the item) Response (Successful Outcome (TI Request received by the Buyer):
    - Responder (Buyer) will only indicate the initial TI data received from the Seller (this may look like the Responder is still the last owner).
    - Responder may include a requestLineNumberMessage explaining that the item was returned.

6. **Expected Failure Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is unmet.
Seller Response - Failure Outcome:
No response or response other than the Successful Outcome response.
Buyer (that returned the item) Response (Failure Outcome)
No response or response other than the Successful Outcome response.

7. **Considerations:**
Clearly state information that may be helpful for proper implementation or operation.

a.

REQ38 - Valid methods of TI Request / TI Response exchange.

email, OpenAPI and DIDComm are the current recognized methods of TI request/Response exchange.

Category

Connectivity

Source Document

PDG Blueprint Chapter 5

Source ID

Recommendations

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   - TI Request JSON and TI Response JSON are sent based on the least capability of the parties involved.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   - Trading Partners have agreed on a method of trace exchange.
   - Connectivity information shared between Trading Partners indicates the method of exchange.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   - The method used to exchange TI Requests and TI Responses defaults to the lowest level maturity capability of the parties involved.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   - Pass Criteria:
     - A TI Request or TI Response is exchanged using the lowest level of capability of the parties.
   - Fail Criteria:
     - Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   - Trading Partner has provided a connectivity method supported.
   - Requesters can send a TI Request to the proper Responder.

- Responders can send a TI Response back to the TI Requester.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   - Trading Partner has provided a connectivity method that is not supported.
   - Requester cannot send a TI Request to the proper Responder.
   - Responder cannot send a TI Response back to the Requester.
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   -

REQ39 - If a digital credential is used, checks are performed to verify the credential.

The use of OCI-specified digital credentials is currently optional in the TI Request and TI Response schemas. However, if trading partners are using credentials, the following checks are made:
- Issuer is Authorized
- Valid Issuer Signature
- Valid Trading Partner Signature (on the credential presentation)
- Credential has not been tampered with
- Credential has not been reused
- Credential has not been revoked
- Credential is not expired
- Credential Presentation is not expired

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 5

Source ID

Figure 12

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. If the optional dscsaCredentialPresentation is provided, the Credential Presentation is verified.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. TI Request or TI Response passes data format and mandatory element checks as per TI Request or TI Response schema.
   b. The TI Request or Response includes a dscsaCredentialPresentation.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   If a dscsaCredentialPresentation is provided in the TI Request or TI Response, the following checks are made:
   - Issuer is Authorized
   - Valid Issuer Signature
   - Valid Trading Partner Signature (on the credential presentation)
   - Credential has not been tampered with
   - Credential has not been reused
   - Credential has not been revoked
   - Credential is not expired
   - Credential Presentation is not expired

.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      i. Provided Credential Presentation passes the credential checks.
   b. Fail Criteria:
      i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Maturity Level 1:
   a. Responder:
   - No action on credential is expected at maturity level 1.
   - Responder performs manual Identity and ATP, ATP-Equivalent or DSCSA Authority checks.

   b. Requester:
   - No action on credential is expected at maturity level 1.
   - Requester performs manual Identity and ATP or ATP-Equivalent checks.

   Maturity Level 2 or 3:
   - Credential presentation is checked, and the results of the check are included with the presentation of the TI Request or TI Response.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   Maturity Level 2 or 3:
   - **Responder:**
     - Responder TI Response of:
       - responseMessageCode = “xx1”
       - responseMessageDescription = “Credential verification failed”
       - or,
       - Responder performs manual Identity and ATP, ATP-Equivalent or DSCSA Authority checks.
   - **Requester:**
     - Responder TI Response of:
       - Need mechanism for Requester to respond to a failed Credential

- or,
- Responder performs manual Identity and ATP, ATP-Equivalent or DSCSA Authority checks.

7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   a.

REQ40 - TI Request for Compliance Audit purposes.

Testing and Audit (Compliance Audit) request reasons may result in redacted information due to confidentiality issues.

Category

TI Response

Source Document

PDG Blueprint Chapter 5

Source ID

Figure 11

Acceptance Criteria

8. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. A TI Request with investigationReasonAttestation = “Compliance Audit” is received.
9. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. Must satisfy Req02
   b. TI Request passes schema validation (data format and mandatory element checks as per TI Request schema).
10. **Testable Condition:**
    Describe how the acceptance criterion can be tested objectively.
    Specify the steps, procedures, or tools used for testing.
    Responder sends TI Response with:
    a. TI based on TI Request, or
    b. TI Response with responseMessage = “xx3 Compliance audit Request received”
11. **Pass/Fail Criteria:**
    Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
    Include any thresholds, tolerances, or standards that must be met.
    a. Pass Criteria:
       i. Responding system responds with requested information or responseMessage = “xx3 Compliance audit Request received”
    b. Fail Criteria:
       i. Failure Of Pass Criteria
12. **Expected Successful Outcome:**
    Clearly state the expected result or behavior when the system interaction requirement is met.

TI Requests will result in:

a. TI Responses conforming with the TI Response schema (or response outside the electronic network) for each tiRequest, or
b. responseMessage = “xx3 Compliance audit Request received”

13. Expected Failure Outcome:

Clearly state the expected result or behavior when the system interaction requirement is unmet.

a. No Response provided.

14. Considerations:

Clearly state information that may be helpful for proper implementation or operation.

a.

REQ41 - Exception messaging

Figures 4, 5, and 6 [of PDG Blueprint Chapter 5] illustrate error messages provided by the Responder. Requesters can correct errors in their request and submit the corrected TI Request. If the Requester is unable to submit an acceptable Request, they can use the Contact Information provided in the TI Response Party section of the TI Response message to contact the Responder.

Supplementary messages can be provided addressing the entire Request, or for individual Requests identified by the Request Line Number. It is envisioned that standard supplementary and error messages will be developed as part of the TI Request / TI Response standardization process. The following messages are illustrative and are applied at the Request set and individual Request levels.

Category

Exceptions Processing

Source Document

PDG Blueprint Chapter 5

Source ID

Exception Processing and Supplemental Messaging

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. An issue has occurred with a TI Request.
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. TI Request or TI Response does not pass data format or mandatory element checks as per TI Request schema, or a parameter error has occurred.
3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   i. See individual requirements and their Testable Conditions
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. Responder provides the appropriate code and message in either the *responseMessage* or *requestLineNumberMessage*.
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

- Responder contacts the Requester outside of the EDDS system, or:
- TI Response includes an appropriate error code and description.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   a. No response is given.
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   a.

REQ42 - Establishing the Requester's or Responder's ATP status.

The digital credential architecture adopted by PDG is leveraged in TI Request/Response interactions to support an efficient, interoperable, electronic, and decentralized eco-system. Digital credentials in TI Requests or Responses provide cryptographically verifiable Identity and authority information of the entity.

Requesting TI or Responding to TI Requests.

However, PDG recognizes that individual trading partner pairs may address “credentialing” outside the PDG-defined DSCSA EDDS network. Two are possible, however they fall outside the PDG-defined EDDS network architecture for Tracing:

- KYC/KYS and direct connections: Employs the same processes TI/TS exchange relies on for trading partner pairs to accomplish authentication and authorization through their existing processes for establishing a trading partner’s identity and ATP status AND by establishing direct and secure connections between their systems.
-
- Ad-Hoc credentialing process: For an entity to respond to a PI Verification or Tracing request, they must first ascertain the requester’s identity and “authorized” status. This process could be initiated using the Requester’s “Contact Information”. The trading partners would then perform their internal processes for establishing a trading partner’s identity and ATP status. Each subsequent TI Request will trigger this same process.

Category

Authentication/Authorization

Source Document

PDG Blueprint Chapter 5

Source ID

Credentialing for Tracing section

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. .
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   TI Request passes data format and mandatory element checks per TI Request schema.
   a. A DSCSA Credential Presentation is not provided.
   b. A DSCSA Credential Presentation is provided.

3. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   i. .
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:
      i. .
   b. Fail Criteria:
      i. Failure Of Pass Criteria
5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   a. A DSCSA Credential Presentation is not provided.
      i. Responder follows internal process to ascertain Requester's ATP status prior to responding.
      ii. Responder responds with TI Response.
   b. A DSCSA Credential Presentation is provided.
      i. Responder system performs credential checks to ascertain Requester's ATP status prior to responding, or;
      ii. Responder follows internal process to ascertain Requester's ATP status prior to responding.
      iii. Responder responds with TI Response.
6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   a. Responder unable to establish ATP, ATP-Equivalent or DSCSA Authority status of the Requester will follow their internal process and may choose to:
      - Contact Requester using the Contact Information provided in the TI Request.
      - Not respond to the TI Request.
      - Respond to the TI Request
      - Other internally determined action.
7. **Considerations:**
   Clearly state information that may be helpful for proper implementation or operation.
   a.

REQ43 - Authentication / Authorization of TI Requester or TI Responder.

The preferred method of checking the authenticating (determine identity) and authorizing (determine ATP, ATP-Equivalent, DSCSA Authority status) of the Requester or Responder is using W3C standard digital credentials (see Chapter 6, Credentialing) as documented by OCI open specifications [14]. During the transition to digital credentials, TI requests and TI responses may be exchanged without the proper digital credential, leaving the receiving party with the task of manually:

- authenticating the identity of the Requester or Responder who sent the message
- authorizing the requesting or responding entity by checking their TP, ATP-Equivalent or DSCSA Authority status

Category

Authentication/Authorization

Source Document

PDG Blueprint Chapter 5

Source ID

DSCSA Authentication and Authorization Checking section

Notes

[14] OCI: Open Credentialing Initiative: www.oc-i.org.

Acceptance Criteria

1. **Acceptance Criterion:**
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   a. .
2. **Prerequisites:**
   Specify any conditions that need to be met before the interaction can proceed.
   a. TI Request passes data format and mandatory element checks as per TI Request schema.
   b. dscsaCredentialPresentation is provided or dscsaCredentialPresentation is not provided
3.
4. **Testable Condition:**
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   i. .
5. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   a. Pass Criteria:

i. .

b. Fail Criteria:
    i. Failure Of Pass Criteria

6. **Expected Successful Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is met.

    a. Responder system performs credential checks to ascertain Requester's ATP status prior to responding, or;
    b. Responder follows internal process to ascertain Requester's ATP status prior to responding.
    c. Responder responds with TI Response.

.

7. **Expected Failure Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is unmet.

    d. Responder unable to establish ATP, ATP-Equivalent or DSCSA Authority status of the Requester will follow their internal process and may choose to:
        - Contact Requester using the Contact Information provided in the TI Request.
        - Not respond to the TI Request.
        - Respond to the TI Request
        - Other internally determined actions.

8. **Considerations:**
Clearly state information that may be helpful for proper implementation or operation.

REQ44 - Tracing model

Tracing of drug product transfers (identified by GTIN + Serial Number or NDC + Serial Number) is accomplished by a series of TI Request and TI Response interactions. Each TI Response provides the endpoint where the next TI Request can be made.

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 5

Source ID

Tracing Model section

Acceptance Criteria

All Maturity Levels:

Given:

e. TI Request passes data format and mandatory element checks as per TI Request schema.

Expected Outcome:

Successful Outcome[7]:

f. Responder system returns a TI Response message that passes data format and mandatory element checks as per TI Response schema.

or,

g. Responder contacts and provides Response using the Requester's Contact information provided in the TI Request

Failure Outcome:

h. No TI Response is provided,

or,

i. Responder system returns a TI Response message that does not include tiRequestConnectivityInformation for each company identified as a Transfer-To or Transfer-From party in a TI dataset (this TI Response will not pass schema validation).

[7] TI Response includes tiRequestConnectivityInformation for each company identified as a Transfer-To or Transfer-From party in a TI dataset.

REQ45 - Purpose of TI Request

TI Requests may be made for the purposes of:
1. Investigating a Suspect product.
2. Investigating an Illegitimate Product.
3. Investigating recalled product [DSCSA Authority only].
4. Demonstrating tracing capability as part of a compliance audit.

Category

TI Request

Source Document

PDG Blueprint Chapter 5

Source ID

Purpose of Document section

Acceptance Criteria

All Maturity Levels:

This requirement is handled by acceptance criteria for Req 22, 23, 24, 25 & 30

REQ46 – Schema Failure Exceptions

TI Request and TI Response JSON messages are expected to pass checks based on their respective schemas. A change request is being developed to address the granularity of information provided based on a schema check failure. For the time being, the equivalent of a HTTP Status Code 400 will be used.

Category

TI Request, TI Response

Source Document

PDG Blueprint Chapter 5

Acceptance Criteria – TI Request schema verification failure

All Maturity Levels:

Given:

j. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)

k. TI Request fails schema check.

Expected Outcome:

l. Maturity Level 1 or 2:
- Responder returns error codes.

m. Maturity Level 3:
- Responder returns an HTTP Status Code 400.
- Responder returns error codes.
- Could provide an API endpoint to acquire more information about the error(s)

n.

Acceptance Criteria – TI Response schema verification failure

All Maturity Levels:

Given:

o. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)

p. TI Response fails schema check.

Expected Outcome:

q. Requester contacts Responder using the Contact Information Responder provided in the TI Response message or other means to notify the Responder of the schema check failure.

r. Upon mutual agreement, Responder may provide a corrected TI Response, or both parties make corrections in their respective records.

Appendix

The following information is for reference only. It will be submitted as a change request to PDG to address explicit exception codes and messages.

JSON Schema Failures

JSON validation against a schema is an important step to ensure the integrity and consistency of the data being processed. Here are some common errors in a JSON file that could cause validation to fail when checked against a JSON schema:

1. **Invalid JSON Format:**
   - JSON files must be properly formatted with the correct use of brackets, commas, and colons. A missing or misplaced bracket, comma, or colon can lead to validation failure.
2. **Missing Required Fields:**
   - If your schema specifies certain fields as required, but they are missing in the JSON file, validation will fail.
3. **Type Mismatch:**
   - If the schema specifies a certain data type for a field (like string, number, boolean, object, array, etc.), and the corresponding field in the JSON file contains a value of a different type, validation will fail.
4. **Enum Validation Failure:**
   - If the schema defines an enumeration (a list of allowed values) for a field, and the value in the JSON file is not one of the allowed values, validation will fail.
5. **Format Constraints:**
   - JSON schemas can specify format constraints for strings, like email addresses, URLs, dates, etc. If a field's value doesn't match the specified format, validation will fail.
6. **Minimum and Maximum Values:**
   - If your schema sets minimum and/or maximum values for numeric fields, and the corresponding values in the JSON file don't meet these constraints, validation will fail.
7. **Array Length Validation:**
   - Schemas can define minimum and maximum lengths for arrays. If an array in the JSON file has a length outside these constraints, validation will fail.
8. **Object Property Validation:**
   - If your schema defines specific properties that an object should have, and the JSON object is missing any of these properties, validation will fail.
9. **Additional Properties:**
   - Some schemas might set **"additionalProperties": false** for objects, which means no extra properties beyond what's specified in the schema are allowed. If the JSON object contains additional properties not defined in the schema, validation will fail.
10. **Recursive Structures:**
    - Some schemas might involve recursive structures (objects containing objects of the same schema). It's important to handle these cases properly to avoid infinite loops or other unexpected behavior.

11. **Circular References:**
    - Circular references between objects can lead to validation issues, especially if the schema doesn't account for such scenarios.
12. **Schema Itself Invalid:**
    - If your schema is not valid, it might fail to correctly validate JSON files. Ensure your schema is well-formed and correctly written.
13. **Custom Validation Rules:**
    - If your schema includes custom validation logic (using keywords like **"if"**, **"then"**, **"else"**, **"anyOf"**, etc.), failures in these conditions could cause validation errors.

It's important to have clear error-handling mechanisms in place to handle these validation failures gracefully, providing helpful feedback to users about what specifically went wrong in the JSON data.

JSON Schema Failures – Errors

The error codes used in JSON schema validation libraries are usually associated with the JSON schema attributes that failed to validate in the provided JSON data. These error codes help you pinpoint which part of the schema validation failed and provide a more descriptive context about the issue. Here's how these error codes are related to the JSON schema attributes:

1. ****`"required"`:****
   This error code indicates that a required property is missing in the JSON data. The `"required"` attribute in the schema specifies which properties are mandatory.

2. ****`"type"`:****
   This error code signifies that there is a type mismatch between the expected data type specified in the `"type"` attribute of the schema and the actual data type of the value in the JSON data.

3. ****`"enum"`:****
   This error code indicates that the value in the JSON data doesn't match any of the allowed values specified in the `"enum"` attribute of the schema.

4. ****`"format"`:****
   This error code suggests that the value in the JSON data doesn't conform to the expected format defined in the `"format"` attribute of the schema, such as for dates, email addresses, URLs, etc.

5. ****`"minimum"`, `"maximum"`, `"minLength"`, `"maxLength"`, etc.:****
   These error codes relate to violations of the numeric or string length constraints set by attributes like `"minimum"`, `"maximum"`, `"minLength"`, `"maxLength"`, etc.

6. ****`"properties"`, `"patternProperties"`, `"additionalProperties"`:****
   These error codes are tied to object property validation. `"properties"` attribute specifies expected properties, `"patternProperties"` validates

against patterns, and `"additionalProperties"` deals with any extra properties not defined in the schema.

7. **`"items"`, `"minItems"`, `"maxItems"`, `"uniqueItems"`:**
   These error codes relate to array validation. `"items"` attribute specifies the expected item schema, `"minItems"` and `"maxItems"` define array length constraints, and `"uniqueItems"` enforces uniqueness.

8. **`"anyOf"`, `"allOf"`, `"oneOf"`:**
   These error codes pertain to conditional validation, indicating which conditional clause failed. `"anyOf"` requires at least one condition to be satisfied, `"allOf"` requires all conditions to be satisfied, and `"oneOf"` requires exactly one condition to be satisfied.

9. **`"dependencies"`:**
   This error code is associated with dependencies between properties. If a property's dependencies are unmet, this error code is triggered.

10. **`"custom"` or `"user_defined"`:**
    Depending on your implementation, you might define custom error codes to handle specific validation scenarios beyond the standard attributes.

By examining the error code and understanding the context in which it occurred, you can easily identify which part of the JSON schema validation failed and take appropriate action for error handling and reporting.

JSON Schema Failures – Error Examples

Note: *The following is a generic treatment of JSON errors and needs to be adjusted to represent TI Request or TI Response messages.*

The way error messages are structured and whether the entire JSON is repeated with inserted error and message information can vary depending on the implementation and design decisions of the system handling JSON schema validation. Here are a couple of common approaches:

Verbose Error Responses:

Some systems provide verbose error responses that include the entire JSON document along with detailed error information for each validation failure. In this approach, the error response might include the entire JSON data with additional fields inserted to highlight where the errors occurred and the corresponding error messages. This can be helpful for developers to quickly identify the problematic parts of the JSON and the specific issues that caused validation failures.

Minimal Error Responses:

Other systems might opt for more concise error responses that focus solely on the validation errors without repeating the entire JSON. In this case, the error response would typically include a list of error objects, where each object contains information about the specific error, the field where the error occurred, and the error message. The JSON data itself might not be repeated in the error response.

The choice between these approaches depends on factors such as the intended audience for the error responses (developers vs. end-users), the desired level of detail, and the available error handling infrastructure.

Here's an example illustrating both approaches for a "Missing Required Field" scenario:

Verbose Error Response (Repeating Entire JSON):

```
{
  "error": "validation_failed",
  "message": "JSON schema validation failed.",
  "errors": [
    {
      "field": "name",
      "error": "required",
      "message": "The 'name' field is required but missing."
    }
  ],
  "input_json": {
    "age": 30,
    "email": "bob@example.com"
```

```
  }
}
```

Minimal Error Response (Not Repeating Entire JSON):

```
{
  "error": "validation_failed",
  "message": "JSON schema validation failed.",
  "errors": [
    {
      "field": "name",
      "error": "required",
      "message": "The 'name' field is required but missing."
    }
  ]
}
```

Both approaches have their merits. The verbose approach provides more context for understanding the validation errors within the context of the entire JSON structure, while the minimal approach keeps the response concise and focused on the errors themselves. The choice depends on your application's requirements and the level of detail you want to provide in your error responses.