URS and FRS Authoring Workshop

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Intended Audience

This training is intended for Validation Engineers, Validation Leads, System Managers, Business Process Owners, Business Analysts, Quality Assurance Reviewers who create, review, or approve User and Functional Requirements for GxP Systems.

Learning Objectives

The objectives of this training are to understand:

- The different requirement categories
- How the business process flow is used to develop user requirements
- Why, What, Who, and When User and Functional Requirements are developed and used
- The relationship between User and Functional Requirements
- What makes a good User Requirement and Functional Requirement
- How the type of system impacts types of requirements

Agenda

- Requirement Categories
- Requirement Fundamentals
- What Makes a Good Requirement
- Creating User and Functional Requirements
- Requirements by System Type

Requirement Categories

Requirement Categories

Requirement specifications should consider the following requirement categories, as applicable:

- Role / Security
- Business Process Workflow
- 21 CFR Part 11/Annex 11 Compliance
  - System Security
  - Audit Trail
  - Electronic Records and Signature
- System Interfaces
- Data Lifecycle/ Data Flow
- Non-Functional (DR / Backup & Restore)

Requirement Fundamentals

What are Requirements?

- A User Requirement defines what a business user expects to have fulfilled through the operation of a system.

- A Functional Requirement defines what system functionality fulfills the user requirement.

Requirements are not

- Reverse Engineered

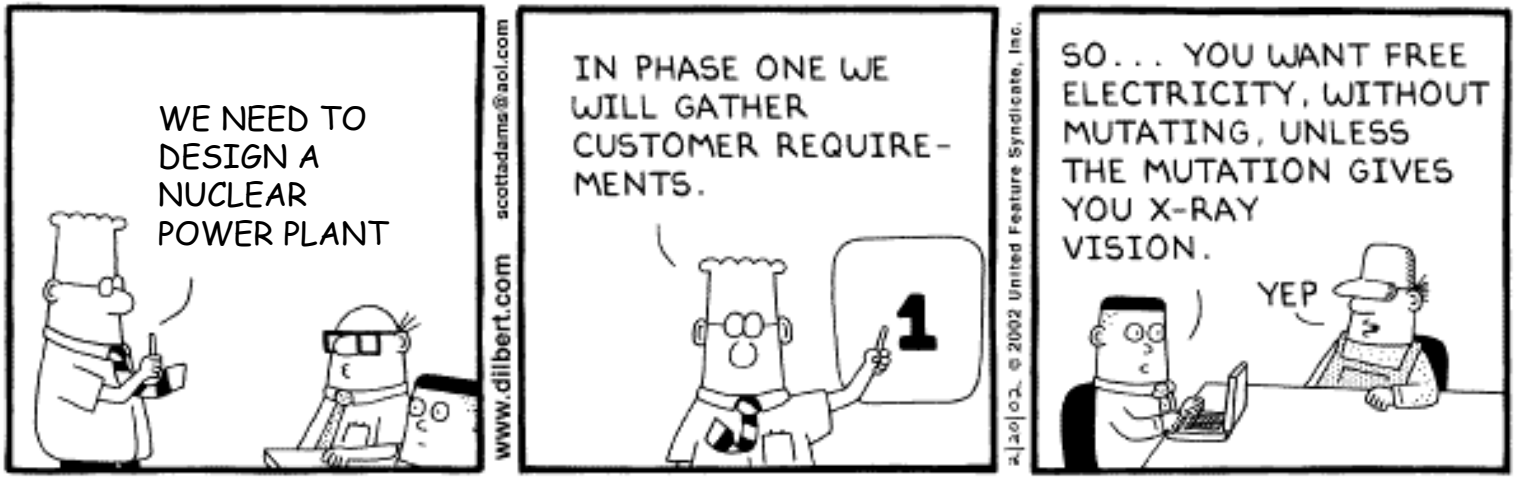
Requirements are not

- Only a Copy of Vendor Documentation

Requirements are not

- Unrealistic

  URS-01: A free computer system that never breaks and is always right.



Why?, When?, and Who?

- **Why** – Know what system is intended to do and design system to the requirements, test to requirements

  Is it designed right and does it work right?

- **When** – At the start of a project or update release
- **Who** – Individual or Team?

What kind of team?

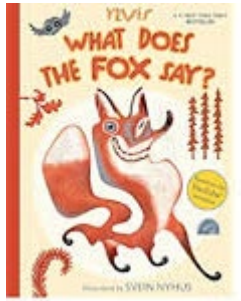
Which team is more successful & why?

Who does SOP-11348 say?

STANDARD OPERATING PROCEDURE

Document No.: SOP-11348 (5.0)
Supersedes: SOP-11348 (4.0)
Page: Page 1 of 20

Title: GxP Computerized System Validation Procedure



4.2. Specifications

	Responsible	Action
4.2.1.	BPO	Defines the user requirements.
		Note: Acts as a global BPO, for enterprise-wide, cross functional systems. The global BPO identifies additional business leads by site or functional area, when required.

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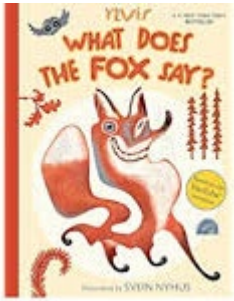

4.2. Specifications

	Responsible	Action
4.2.2	SM	Authors supporting technical documentation, including but not limited to, functional requirements and design specifications.

Who does SOP-11348 say?

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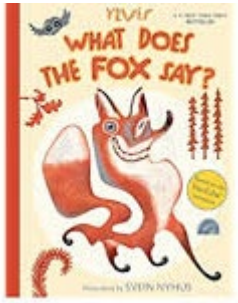


4.2. Specifications

	Responsible	Action
4.2.3	VT	Ensures that the applicable data integrity (e.g., Part 11, and Annex 11), disaster recovery, and business continuity requirements are included in the User Requirements Specification (URS), Functional Requirements Specification (FRS), and Design Specification (DS).

Who Develops the Requirements?

“There is no “I” in URS and FRS.”

- URS Team – BPO, BA, VAL, QA
- FRS Team – SM, BA, VAL, QA

What Makes a Good Requirement?

Good Requirements Are…

Requirements need to be:

- Necessary (For the intended use of the system; not just boilerplate)
- Specific (Clear, unambiguous, with one and only one interpretation)
- Testable (There is way to verify if the system meets a requirement.)
- Traceable (Between requirements and to a qualification test)

Good Requirements Aren't…

Requirements must not be:

- Ambiguous (Using a verb such as "should" or quantifiers such as "most" or "some.")

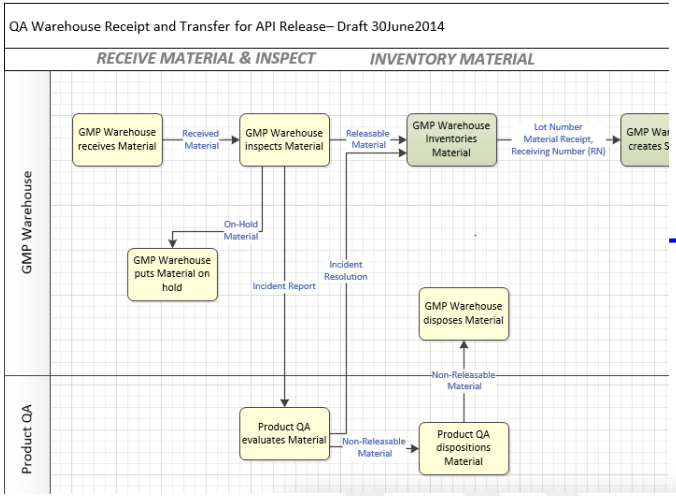
  For Example: "System ***should*** allow the user to enter Contract Lab QA Approval Date for ***some*** CMO samples."

- Compound (Multiple requirements combined into one requirement).

  For Example: "The system must enable reported impurities to be associated with a particular product active. The system sums the reported impurity values to report the Total Impurities."

Creating User Requirements for the Business Process

A Path to Get to the URS



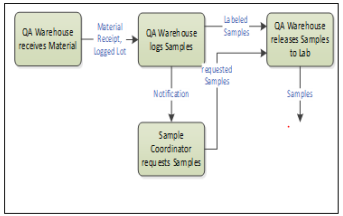
Process Map Narrative

Map # 2: To Be Process for Lot Release of API and DP

Preamble

This narrative describes the process of receipt, sampling, testing, evaluation of testing, and release of API and DP lots.

Sub-section: QA Warehouse receives Material and dispense Sample(s)



Associated Documents:

- SOPs: FCSOP-0017,FCSOP-0093,FCSOP-0019, FCSOP-0025
- Forms: FCF-463,FCF-783,FCF-463,FCF-338

Systems Used:

- LIMS

Triggers:

- Material arrives at QA Warehouse

BPOs: Scott Hebner
SMEs: Kristen Hogg
Data Stewards: tbd

Narrative:

1. QA Warehouse Receives Material
   - Performs incoming Inspection
     - If Material does not pass inspection, notify Product QA:
       - Initiate FCF-463 Incident Report (FCSOP-0375)
       - Log in IR logbook FCF-783
       - Place Material on Hold
       - If Product QA determines material is compromised, Receive Material

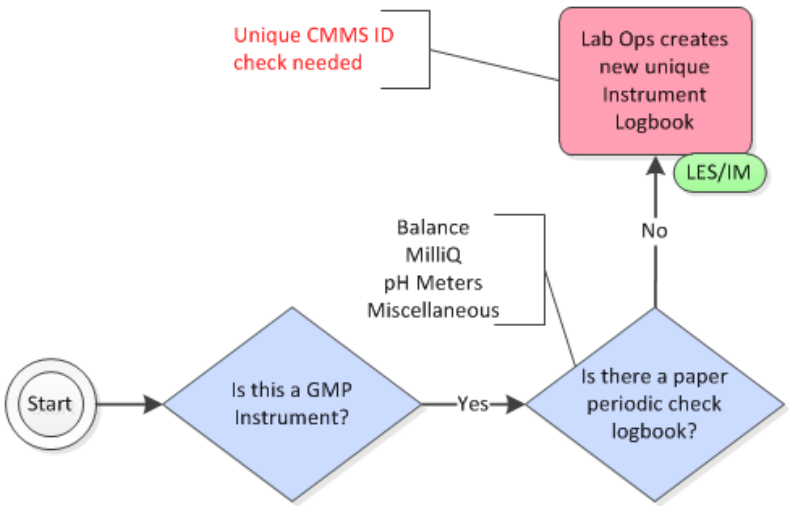
6 USER REQUIREMENTS

6.1 Material Receipt

ID	Requirement
URS-01-01	A GMP Warehouse operator documents the receipt of incoming materials.
URS-01-02	A GMP Warehouse operator records material inspection information.
URS-01-03	A GMP Warehouse operator views incomplete inspection samples.
URS-01-04	A GMP Warehouse operator updates incomplete inspection samples.
URS-01-05	A GMP Warehouse operator is able to attach multiple electronic documents.
URS-01-06	A GMP Warehouse operator reviews material receipt records.
URS-01-07	A GMP Warehouse operator modifies material receipt records.
URS-01-08	A GMP Warehouse operator views failed material inspection records.

Start with the Business Process

1. *Start with the Business Process Flow*.



2. *Add the Narrative*:

New Instrument Logbook Creation

Lab Ops will create the new logbook entry in the LES/IM system. The fields required for each logbook depends on the type of Instrument that they will be used for:

- **Balance Logbook:** CMMS ID, Manufacturer, Balance Type, Daily Weight Check (g), Min Weight (mg), Max Weight (g), daily balance Increment, Instrument Location, and Logbook Creation Date.

Business Process Map & Narrative Functions

Business Process Maps depict:

- **Who**
- does **What** action
- **When** is the action done (triggers to start)

Narratives include these and add:

  - **What** are the controls for the action (e.g. SOPs, required forms)
  - **Why** is this being done (the business capability the action enables)

Narratives do not include:

- **How** the role/actor performs the function using the system
- **How** the system functions
- **How** the system controls the transaction

User Requirement Content

User Requirements describe the following:

- **Who** (which role) performs an action
- **What** action is being performed
- **When** the action is done (where relevant to the requirement)

Deriving the User Requirement From Workflow

Use Narrative:

Lab Ops will create the new logbook entry in the LES/IM system.

To fill in the blanks for the following structure:

Req. # | User Type/Role/Authorized User | performs a business function/operation

URS-01: An Analyst in the Lab Operations group creates an instrument logbook.

Req. # | User Type/Role/Authorized User | must/is able to | perform a business function/operation

URS-02: An Analyst in the Lab Operations group is able to enter a comment.

“Must” & “Is Able To” Examples

5.3.41	When all Approvers have completed their Approval task with a verdict of ‘Approve – Retire’, the system sends the identified Second Level Approvers an Approval task.
5.3.42	Only one of the Second Level Approvers must complete the task.

“Must” & “Is Able To” Examples

11.1.8 Reserve Sample		
URS-35-38.10	N/A	EDM Lab Manager logs Reserve samples.
URS-35-38.20	N/A	EDM Lab Manager stores reserve samples.
URS-35-38.30	N/A	EDM Lab Manager moves and disposes reserve sample inventory.
URS-35-38.40	N/A	A second EDM Lab Manager verifies reserve sample inventory storage, and disposal.
URS-35-38.50	N/A	EDM Lab Manager updates inventory quantity and units for reserve samples
URS-35-38.60	N/A	EDM Lab Manager generates a “Reserve Storage Receipt” report.
URS-35-38.70	N/A	EDM Lab Manager generates an “API Reserve Record” report.
URS-35-38.80	N/A	EDM Lab Manager is able to view Lot Information.
URS-35-38.90	N/A	EDM Lab Manager is able to view verified storage.

URS Writing Style

- Write each URS statement so that it stands on its own, (e.g., even when it is removed from its context).
- Use simple verbs in present tense in constructing statements (e.g., “is”, “does”).
- Avoid using future tense, “soft” verbs (e.g., “will be”)
- Avoid using one-sided conditional phrases such as: “If X, then Y”.

  Instead, define each condition and their resultant action:
  - If “X” is true, <actor> does “Y.”
  - If “X” is false, <actor> does “Z.”

If “X” then “Y” Example

- If “X” then “Y”:
  - The user selects a protocol associated with an active Stability Study from the Stability Study Inventory tab to adjust the inventory.

X

Y

- If not “X” then “Z”:
  - When the user selects a protocol that is associated with a Stability Study that is not active, the user receives an error message.

Not X

Z

Reminder: User Requirements are not “How”

When writing User Requirements do not include:

- How the user performs the function using the system

  The user clicks the Save button to complete the transaction.

- How the system functions

  The system triggers a prompt for the e-signature.

- How the system controls the transaction

  The system saves the data to an SQL database as a read-only record.

Creating Functional Requirements

URS/FRS Relationships

- The relationship between User and Functional Requirements should be more like a **Parent/Child** relationship where the user requirement has one or more child Functional Requirements.

- It is **NOT** like **Identical Twins** where the Functional Requirement is simply a duplication of the User Requirement.

- **No Orphans** - Every Functional Requirement has a corresponding User Requirement.

- **No Surprises** - Functional Requirements should not add business details; they should be in the User Requirement, e.g. specific attributes

URS/FRS Relationship Examples - Twins

Example 1	
URS-02-10	When a column fails the system suitability test, it is automatically moved into “Quarantine” status. (Automatic Control)
FRS-02-13	When a column fails the system suitability test, it is automatically moved into “Quarantine” status.

Example 2	
URS-40	An authorized user can view learning history of subordinate(s)
FRS-40-1	The system allows an authorized user to view learning history of subordinate(s)

URS/FRS Relationship Example – Surprise!

Example 1			
URS-1	A user can view their learning history.	FRS-1-1	The system displays a list of training items completed by the user on the history screen
		FRS-1-2	The system displays detailed full page information of the training item completion on the history screen
		FRS-1-3	The system allows a user to view their pending or overdue training item(s).
URS-2	A Supervisor can view pending or overdue training item(s)of subordinate(s)	FRS-2-1	The system allows an authorized user to report on pending and overdue training item(s) of subordinates.
		FRS-2-2	The system highlights the due dates for overdue items in the report.

URS/FRS Relationship Example – Surprise!

Example 1			
URS-1	A user views self-learning history.	FRS-1-1	The system displays a list of training items completed by the user on the history screen
		FRS-1-2	The system displays detailed full page information of the training item completion on the history screen
URS-2	A user views their pending or overdue training item(s).	FRS-2-1	The system allows a user to view pending and overdue training on their To-Do list.
		FRS-2-2	The system displays ‘Overdue’ for training items that have not been completed by the due date in the users To-Do list.
URS-3	A Supervisor views pending or overdue training item(s)of subordinate(s)	FRS-3-1	The system allows an authorized user to report on pending and overdue training item(s) of subordinates.
		FRS-3-2	The system highlights the due dates for overdue items in the report.

Creating Functional Requirements

Functional Requirements are used to answer questions such as:

- What does the system need to do?
- What does the system need to control?
- What automated tasks does the system need to perform?
- What operational checks does the system need to enforce?
- What authorization checks does the system need to enforce?

Functional Requirements Stucture

Pure system actions are described in the FRS.

<Req. #> The system <action> < the needed system function/operation>

For example:

- The system saves inputs to the database.
- The system prints the daily report at midnight every day.
- The system prevents authorization of a sample until all tests are authorized.
- The system prevents a Lab Manager from dispositioning an API lot.
- The system performs a data validation check on numeric entries.

Functional Requirements Stucture

Pure system actions are described in the FRS.

<Req. #> The system <action> < the needed system function/operation>

For example:

FRS-01: The system opens an Instrument Logbook for the selected instrument type.

FRS-02: The system provides the following fields to create a Balance Logbook for entry:

Number of Units (defaults to 1)
CMMS ID (mandatory)
Manufacturer (mandatory)
Model (mandatory)
Instrument Description (mandatory)

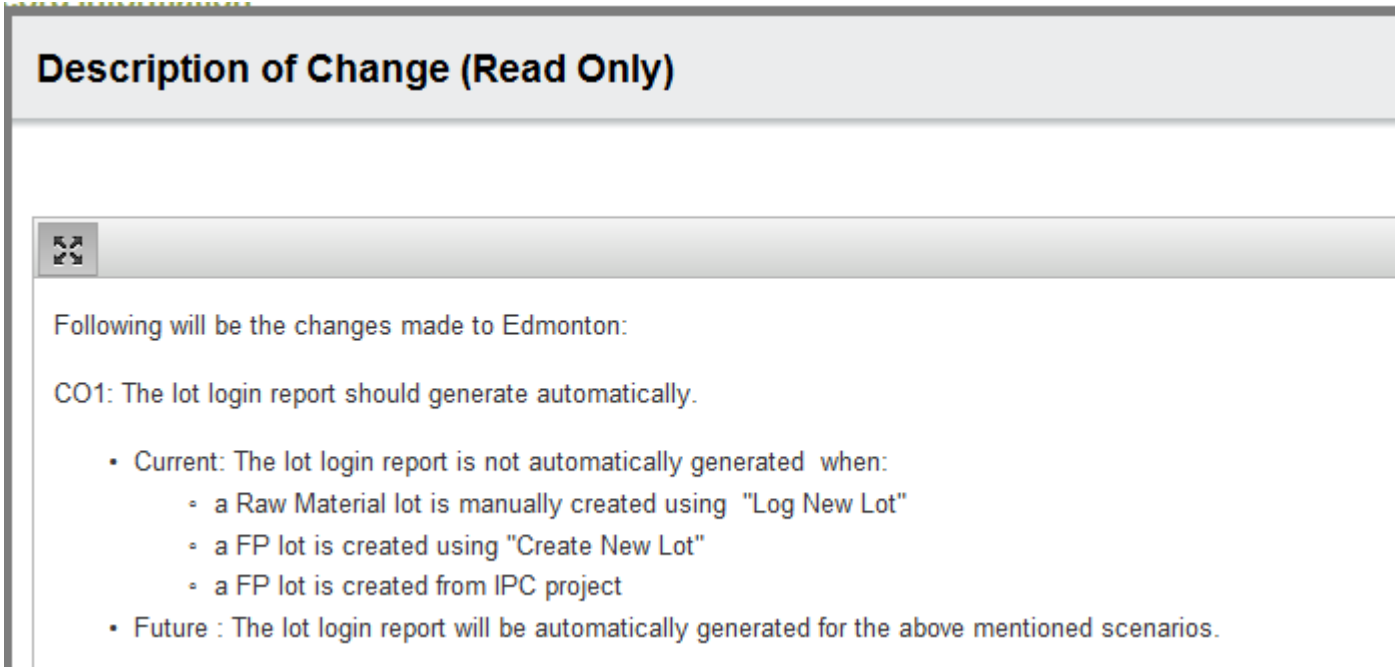
Adding New Requirements for Existing Systems

When updating an existing URS or FRS :

- Understand how the requirements were written initially.
- Identify where the new requirement belongs in the process.
- Try to match the style of the existing requirements to be cohesive.

Example

- Change control to have Lot Login report generated automatically:



Use Trace Matrix to Correlate URS to FRS

URS ID	URS Description	FRS ID
URS-35-04.00	EDM GMP Warehouse Operator and EDM Lab Managers creates a lot for raw materials and EDM Lab Managers create a lot for Finished Products.	FRS-35-04.00 FRS-35-04.10

Existing FRS section

TITLE: GLIMS Functional Requirements Specification

Master FRS	Functional Requirement Specification
FRS-35-03.00	The system automatically generates and prints to a predefined printer the following reports when a lot from EBS is downloaded: • Lot Login Report.
FRS-35-03.10	During automatic lot creation, the system prints the Raw Material Sampling Worksheet to the pre-defined printer.
FRS-35-04.00	The system allows the EDM GMP Warehouse Operator to manually create a RM lot from the 'Log New Lot' link on the role's main visual workflow.
FRS-35-04.10	The system allows the EDM GMP Warehouse Operator and EDM Lab Manager to link a manually created Finished Product lot to an EBS Lot via the 'Gilead Lot Name' and 'EBS Inventory Org' fields within a LIMS Lot.
FRS-35-05.00	The system allows EDM Lab Analysts or EDM Lab Managers to create inventory for an analytical sample.
FRS-35-05.10	The system generates an Analytical Label after the lot and lot samples have been created.

Draft of new FRS requirements

4-1 **Auto Generate reports**		
ID #	**User Requirement**	**Functional Specification**
4-1-1	URS-35-04.00(E04) in GSVAL-0022S will remain as is: EDM GMP Warehouse Operator and EDM Lab Managers create a lot for raw materials and EDM Lab Managers create a lot for Finished Products.	New FRS will be added as FRS-35-04.05 in GSVAL-0021S stating, 1. The system automatically generates a Lot Login report and Sampling Worksheet reports when a Raw Material is logged manually by EDM GMP Warehouse Operator and EDM Lab Managers 2. The system automatically generates a Lot Login report when a Finished Product lot is logged manually by EDM Lab Managers.

Updated Requirements Doc

TITLE: GLIMS Functional Requirements Specification

Master FRS	Functional Requirement Specification
FRS-35-04.00	The system allows the EDM GMP Warehouse Operator to manually create a RM lot from the 'Log New Lot' link on the role's main visual workflow.
FRS-35-04.05	A Lot Login report and Sampling Worksheet reports will be automatically generated when a Raw Material is logged manually by EDM GMP Warehouse Operator and EDM Lab Managers.
FRS-35-04.06	A Lot Login report will be automatically generated when a Finished Product lot is logged manually by EDM Lab Managers.
FRS-35-04.10	The system allows the EDM GMP Warehouse Operator and EDM Lab Manager to link a manually created Finished Product lot to an EBS Lot via the 'Gilead Lot Name' and 'EBS Inventory Org' fields within a LIMS Lot.

Caution: Not all Trace Matrices Created Equal

URS ID	URS Description	FRS #
URS-14-01.00	The Master Data creates a product specification in GLIMS to document the testing requirements, limits as per the specification document that is approved in Document Management System	FRS-14-01.00 FRS-14-02.00 FRS-14-03.00 FRS-14-04.00 FRS-14-05.00
URS-14-02.00	The Master Data completes the E-Signature after creating a Product Specification	FRS-14-06.00
URS-14-03.00	The Master Data configures the Product Specification by adding a Product Grade, Dissolution Q Values, time points and CU values	FRS-14-07.00 FRS-14-08.00

How System Type Impacts Requirement Type

- Examples of System Types
  - COTS vs. Configured vs. Custom

- Specifications Needed:
  - COTS: URS need to validated to its intended use
  - Configured: URS, and possible CS, FRS and DS
  - Custom: URS, FRS, and DS

Exercise 1

Exercise 1 Instructions

1. Create Team
2. Write URS and add the FRS that correspond to each URS.
3. You will write URS/FRS for Label Printer.
4. Submit to me for review

Questions & Answers