Unit 3, 44 McCauley Street
MATRAVILLE NSW 2036

PROC-015

PROCEDURE
PROJECT CONTROL

Prepared by:	**Date:**	**Position:** QA Manager
Checked:	**Date:**	**Position:** Program Administrator
Approved by:	**Date:**	**Position:** CEO

The following ATTACHMENTS form part of this document.

FORM 017 – Project Authority
FORM 018 – Project Plan
FORM-019 - Project History
FORM-024 – Innovation Request Form
FORM-026 - Resource Request R&D

This revision supersedes all previous revisions.
Controlled copy only if stamped with Controlled Copy Stamp and issued with copy number

1. INTRODUCTION

1.1 Purpose of Document

To define and control the process of documenting concepts and then Projects & Quality Planning.

1.2 Purpose of Procedure

To ensure that:

- the resources needed to achieve the objectives are identified and planned;
- communications between participants occurs easily;
- a record of work carried out is retained for later referral and
- to meet regulatory and QA requirements.

To reduce the cost of implementation by reducing costs of corrections and mis-communications

1.3 Scope

Innovation Request is applicable to documenting a concept to determining whether it is worth pursuing by opening a project.

Project control is applicable to;

- any order or contract requiring records,
- any project within a development program;
- any change to operations and or the environment within the scope of the system that may have a significant affect on the company's ability to meet specified requirements.

1.4 Other Documents Referred To

Internal References

FORM 017 – Project Authority
FORM 018 – Project Plan
FORM-019 - Project History
FORM-024 – Innovation Request Form
FORM-026 - Resource Request R&D

F055 - Template – Project -Instruments

PROC-003 - Procedure – Improvement of System/Product
PROC-006 - Procedure – Reviewing the Quality System
PROC-009 - Procedure – Assessing Vendors and subcontractors
PROC-010 - Procedure Document & Record Control
PROC-011 - Procedure- Research & Development

REG-004 - Standards File & register

REG-006 - Register Projects
REG-017 - Bibliography File & register
REG-020 - Design History File & Register
REG-026 - Innovation Request

External References
Nil

1.5 Definitions of Terms Used

Program: The continual development of categories of products and/or processes (e.g. Hip prosthesis, Instruments, Hydroxyapatite etc) that continues for the entire life of the products and/or processes. This is carried out through projects that have individual end points and a stated set of outputs or deliverables. Programs are controlled by senior management and are wider in scope than a project.

Project: An individual development that has an end point defined by project requirements. It must be part of a program.

CEO: Chief Executive Officer

CTO: Chief Technology Officer

1.6 General Responsibility / Authority

The CEO or CTO have the authority to delegate responsibility to other people to carry out the work. The following people are referenced in responsibilities in the tasks below.

Program Manager: The person responsible for a program. This person is normally part of senior management (CEO or CTO).

Program Administrator: A person authorised by the Program Manager to administer a program. The Program Administrator can be the Program Manager. This person is responsible for:

- approving commencement & closing of projects;
- determining and informing management of the program status;
- maintaining program records.

The Program administrator does not make major decisions, especially technical; this is the Program Manager responsibility.

Project Manager: The person responsible for the project and its decisions. This person is often referred to as the owner.

Project Administrator: The person responsible for maintaining project records.

1.7 Project Folder Structure

The folder structure is the same for both hard copy & soft copy. Any documents should be in the same sections as listed below. These sections can have sub-folders. The hard copy is the master copy because it contains the signatures.

Work in Progress: Contains incomplete work. This is a folder and this is to be emptied before the project is closed. Items are not stored unless transferred to Output Documents or History.

Project Administration: Contains Project Authority, Requirement attachments, Project Plan and minutes of any status meetings. These are quality records.

Output Documents: Final copies of any documents listed on plan as an output document. The original document will be removed for filing elsewhere e.g. Design History File records and Device Master Record Drawings etc. Refer to PROC-010 Procedure – Document & Record Control for details. These are Quality records. A copy or cover to be left in the project.

History: Contains Project History Sheet and copies of correspondence, design reviews, design analysis, reviewed/retained drafts & calculations etc. These are Quality records. The FORM-019 Project History sheet contains Date, History (events, documents, records etc) and record ID/Doc. Ref.

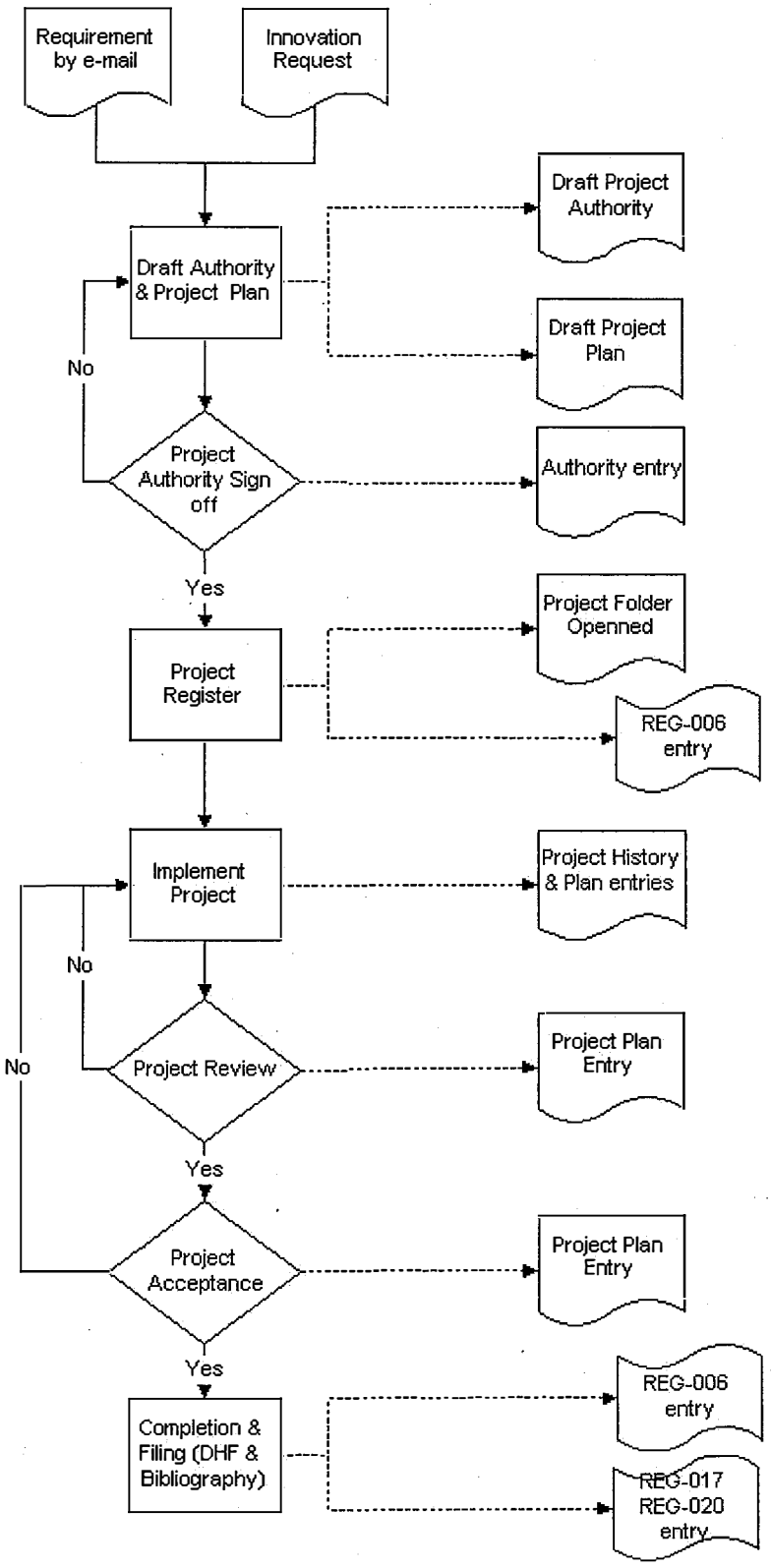
All documents or records are referenced via its document reference number (including issue level) or record ID. Where a record will be referenced elsewhere, this record ID consists of the project number, dash nnn. i.e. PR XX-NNN-nnn where PR XX-NNN is project number (see section 2.2 for details) and nnn is the next sequential number from FORM-019 Project History Record.
NOTE: Unimportant records that are not referenced should not be numbered even though kept as historical records.

Bibliography: Contains documents from outside published sources. It is a temporary section, the section is to be emptied before the project is closed and transferred to REG-004 Standards File & register or REG-017 Bibliography File & register. Refer to Section 6 of PROC-010 Procedure – Document & Record Control for details. These are not quality records as they can be regenerated from external sources from the references. These documents should be registered and filed immediately so that they can be referenced in the project. The section is only for easy access while project is open.

Quality records are under archiving control and cannot be destroyed until archiving period is completed per PROC-010 Procedure – Document & Record Control.

2. PROCEDURE – PROJECT CONTROL

Flow Chart



2.1 Preparing & Planning for a Project

Responsibility
Project Manager,
Project Administrator

Purpose
The Project Authority and Plan allows for determination of project authorisation, control of the project, to determine resources & problems etc early. This stage is done before authorising the commencement of a project.

Task

1. The person requesting a project shall fill out a Project Authority sheet (FORM 017) or similar document (which can be combined with the plan e.g. F055). This shall contain the following information about the project:
   - Project Name;
   - Program / Customer (can be internal);
   - Date Required;
   - Scope of the project and product Requirement Specifications Listing or Locations;
   - Reasons for project

2. A Project Plan is prepared. If the project is small, it can be combined with the Project Authority. It should contain, where applicable, the following:
   - A detailed outline of the expected outputs or deliverables of the project (Product, DMR & DHF).
   - a description of any activities or procedures that must be carried out to meet specified requirements;
   - details of all progressive tests, measurements or inspections that must be carried out to demonstrate conformance to specified requirements as required;
   - details of all final tests, measurements and inspections that must be carried out for completion of evidence of conformance when applicable;
   - standards of workmanship as required;
   - cross references to existing quality procedures and work instructions if appropriate;
   - people responsible for activities;
   - estimated time for completion of activity to help tracking progress (if possible);
   - interactions with other existing, completed or future projects;
   - estimated costs & materia usage (if possible).

Project Plans can be in any format as projects are so variable. This can be checklists or Gantt charts etc. For general projects, FORM 018 can be used as a template. Refer to PROC-011 Procedure- Research & Development for more details of tasks to be included in the plan.

3. The Project Manager approves the plan before submitting it to Program Manager or Administrator for authorisation. In the case of a contract or order, the Project Manager is responsible for seeking written approval of the plan from the CEO & client before commencing the work.

Documents or Records to be Produced

Project Authority

Project Plan

2.2 Authorising & registering a project

Responsibility
Program Administrator

Task

1. The Project Authority Sheet is to be checked that enough information has been supplied to start project especially in the Scope section.
   The Project is to be authorised & dated by Program Manager or Program Administrator.
2. A person shall be designated as Project Manager and Project Administrator. The Project Administrator can be any of these above roles.
3. The Project is registered in the Projects Register (REG-006) recording:
   - Project number (PR XX yyy where XX is the program & yyy is next consecutive number),
   - Project Name/Description,
   - Project Manager
   - Project Administrator,

   The following column are used later:
   - Date Completed,
   - Final Status.
4. The Program Administrator can appoint a person to raise a project folder to hold project information & history, see Section 1.7 Project Folder structure.

The approved quality plan is issued under the control of the Project Manager to those needing it, including the client.

Documents or Records to be Produced

FORM-017 Project Authority is filled out with any attachments.

Entry in Register REG-006 Register Projects

2.3 Implementing, review, modification & documentation.

Responsibility
Project Manager,
Project Administrator

Task

Implementation

The project is implemented as per the plan.

A Project Time Record sheet can be filled out, if time data on the project is required. This is not a quality record.

As stages are completed, these are to be signed off & dated on the project plan with any other relevant information added.

Results of reviews and completion dates should be recorded.

If dealing with outside vendors or subcontractors, use an approved subcontractor or evaluate a new subcontractor per PROC-009 Procedure – Assessing Vendors and subcontractors. Use correct Letterhead on purchase order data.

Modification

Any amendments to the plan are agreed with stakeholders. Records of all discussion and correspondence are kept with the project. At a minimum, a review session with the program manager or administrator should be undertaken and documented (email is sufficient).

Modifying or re-issuing updated plans & information is the responsibility of the Project Manager. These will be under issue control if re-issued with old issues retained but marked "Cancelled" or Obsolete" especially they may contain records of signatures.

Documentation

The project has several types of records

- Project Administration: Authority (including product requirements, noted, attached or referenced [REQS]) & Plan.
- Output Documents
  - Device Master Records (DMR): These are the specification & drawings of the product. These documents are to be registered as part of Device Master Record, see PROC-010 Procedure Document & Record Control.
  - 'Design History File' records (DHF): These documents demonstrate the product (design) complies with requirements but are not part of Device Master Record e.g. verification, validation risk analysis reports etc. Records are numbered and recorded in the Output section of the Project Plan in a similar manner as Project History; (DHF XX-yyy-zzz where XX is the program, yyy is the project number & zzz is the next consecutive reference number). Electronic files to include this project DHF number. Documents are to be registered in Design History File Register REG-020 and documents transferred before closing the project.
- Project History: A Project History Sheet is to be filled out, as the project progresses, to record information (including dates & personnel) that is not documented elsewhere.
  Records can be numbered (for easier referencing) and recorded in the Project History Sheet (PR XX-yyy-zzz where XX is the program, yyy is project number & zzz is the next consecutive reference number). Electronic files to include this project history number.
- Bibliography: These are external documents that are referenced by the project.

Documents or Records to be Produced
Entries on Project Plan
Copies of records filed in history section the project.

2.4 Resources & Training

Responsibility
Project Manager,
Project Administrator

Task

The Project Manager shall ensure that adequate resources are available. . Resources can be requested on FORM 026 Resource Request R&D Form. The Document Number is from the project file History

All staff involved in implementing the plan are to be adequately qualified or experienced, or receive training, and understand the plan.

Documents or Records to be Produced
Nil

2.5 Project Review

Responsibility
Project Manager,
Project Administrator

Purpose (if needed)
One of the purposes of a project file is that someone who did not work on the project can determine what occurred and the reasons for decisions if the product has to be revised later. This task determines if all tasks are complete and the information is useful later.

Task
Have someone else who is competent to understand the project system check that each stage of the project is complete and correct. That person then signs and dates if accepted.

Determine if:

- Project Authority is complete including requirements (including attachments) and reasons for project;
- Project requirements are included with revisions and also signed & dated;
- Project Plan included;
- Each stage of project plan has been completed & signed off;
- Each stage has its referenced records included or location referenced;
- The project scope has been met. Product requirements are often a separate task and documented in the file and not part of this check.
- All Output Specification, drawings etc have been approved, registered and transferred to Device Master Record , see PROC-010 Procedure Document & Record Control;
- All DHF documents have been approved, registered and transferred to Design History File REG-20, see PROC-010 Procedure Document & Record Control. Note: Software copy is preferred in PDF format so that it shows the signatures. A copy of the front page to be left for easy reference;

- Project history summary and history records are included;
- 'Work in Progress' & Bibliography sections have been emptied and closed. Refer to 1.7 Project Folder Structure.

Correct any deficiencies and sign off Completion Check on FORM 018 Project Plan.
On completion, the Project Plan is signed off & dated.

Documents or Records to be Produced
Entry in 'Project Plan Data is Complete' & 'Project Manager Completion Check'on FORM 018 Project Plan.
Possible REG-020 entry

2.6 Project Acceptance

Responsibility
Project Manager,
Project Administrator
Program Administrator

Task
Determine if customer (can be internal) is satisfied with the output. This will determine final Project Status.

Documents or Records to be Produced
Entry 'Final Status'

2.7 Completion & Filing

Responsibility
Project Manager,
Project Administrator
Program Administrator

Task

1. The Project Authority is completed by filling in;
- Date Completed.
- Time Taken (optional),
- Material Cost (optional)'
- Final Status,
- Completion Approval by Program Manager / Administrator.

2. The Project register is completed for;
- Date Completed,
- Final Status.

3. The hardcopy Project Folder with any other records of conformance (verification/validation results etc) become a quality record and are kept in the Completed Projects file as long as specified for this type of Quality records.
4. The softcopy Project folder is transferred to History section of the Server.

Documents or Records to be Produced

Entry in Project Authority sheet
Entry in Project Plan

Entry in Projects Register
Completed Project Authority & Project plan and records.

2.8 Cancelling a Project & Filing

Responsibility
Project Manager,
Project Administrator
Program Administrator

Purpose
If it is decided to close a project, then cancel in a controlled manner with records.

Task
Record the project is cancelled in Scope on the Authority giving reasons.
Mark up the plan showing stages cancelled.
If Authority references another document that transferred control to the project e.g. corrective action etc), update this document with new status.
Complete the project documentation as per 2.7 above.

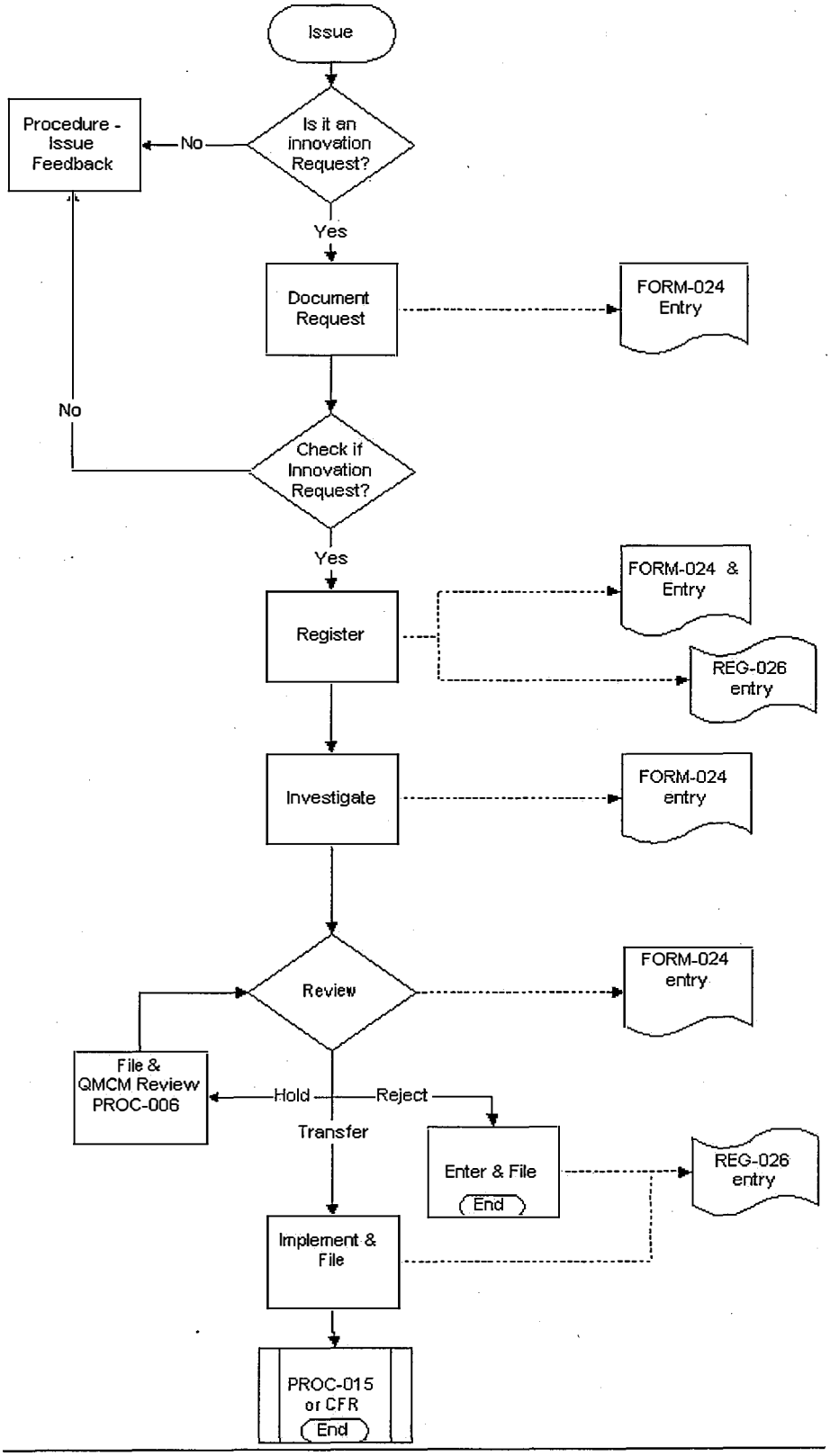
Documents or Records to be Produced

Entry in Project Authority sheet
Entry in Project Plan

Entry in Projects Register
Completed Project Authority & Project plan and records.

3. PROCEDURE – INNOVATION REQUESTS - IR

Flow Chart



Innovation Requests (IR) - are when a suggestion is made for improvement of a product or a new product where it is not related to a complaint or safety issue. The IR's purpose is to determine if work & resources should be spent on an idea and if so transfer to a project etc and is a method of documenting the incubation stage of R&D before design controls apply when it comes under project control.

3.1 Documenting the Request

Responsibility: Anyone

Task

Determine if the request is within the scope of an Innovation Request as above. If so, enter the information on FORM-024 – Innovation Request Form. If there is a complaint or safety issue, go to PROC-003

Documentation
Prepare on FORM-024

3.2 Initial Assessment & Registration

Responsibility: Program Administrator, Production & Engineering Manager

Task

Check enough information supplied.

Check it is within the Scope of an IR and no safety issues are raised. If not acceptable, transfer to CCR, CFR or CAR (see PROC-003) and destroy request to stop confusion.

Register the IR in REG-026 & enter number on form.

Determine who will carry out the Investigation.

Documentation
Entry on FORM-024
Entry in REG-026

3.3 Investigation

Responsibility: Person designated by Program Administrator or Production & Engineering Manager

Task
Investigate the request to determine the feasibility and record the results.
This can include carrying out an preliminary hazard analysis, see PROC-019 Risk Management of medical devices.
Enter conclusions & recommendations

Documentation
Entry in Investigation & Conclusions on FORM-024
Include reasons for Rejection

3.4 Review by CEO or CTO

Responsibility: Program Administrator or Production & Engineering Manager

Task
CEO or CTO is to review to determine acceptance of conclusions & recommendations. Based on these results, the innovation is either rejected, placed on hold (i.e. not implemented but not rejected for the present) or to be implemented by transferring to a project or CFR.
If not accepted, supply reasons.

Documentation
Entry on FORM-024

3.5 Implementing and Filing

Responsibility: Program Administrator or Production & Engineering Manager

Task

If transferring for implementation, raise transfer document e.g. CFR or project (see PROC-015 to generate project authority, plan & to register) and enter onto Form. The IR number is to be referenced on the transfer document. Note date of completion on form & IR register REG-026 and file in IR register.

If rejecting, note rejection on form with date of completion on form & register and file in IR register REG-026.

If holding, do not enter dates but hold in register.

Documentation
Transfer documents
Entry on FORM-024
Possible entry in REG-026

3.6 Reviewing Innovation Requests on Hold

Responsibility: Program Administrator or Production & Engineering Manager

Task
Review at Quality Management Committee Meetings, see PROC-006 Procedure – Reviewing the Quality System. When a decision has been made, complete the IR as per previous section above.

Documentation
Minutes of meeting.

APPENDIX A RECORD OF CHANGES

Issue No.	RECORDED AMENDMENT	DATE	DCN #
1	Release	3/6/03	0076
2	Moved old section 2.2 Planning before registering to improve control and planning. Allow combining Authority & Plan. Added Section 2.8 for cancelling project to make process clearer. 1.7, 2.4 & 2.5 Separate Output documents into DMR & DHF to make process clearer Change Project Leader to Project Manager.	17/3/04	0103
3	Added sect. 3 Innovation Request – IR. Exchanged Sections 2.3 & 2.4 as clearer. New Section 2.3, added reference to FORM-026 Resource request. Added Flow charts		