

			Set-Up Manuals (Work Instructions)
QMS GI-M17	Rev A	Date 05-09-12	Procedure Authority: Production Manager

Purpose: The purpose of this procedure is to establish a consistent manner by which we establish, maintain and utilize “Set-Up Manuals” (or work instructions), for work processes in our production areas.

Scope: The scope of this procedure includes initial creation, document control, the log-out and log-in process and controlling changes to Set-Up Manuals and the Document Control system.

Responsibility: The Production Manager is responsible for creation, accuracy and effectiveness of Set-Up Manuals. The Quality Manager is responsible for Document Control.

Definitions:

Set-Up Manual = (Often referred to as “Work Instructions”); This is typically a 3 ring binder, containing vital “job specific” information, to enable good consistent set-ups, operations, and workmanship across all operators and shifts.

Reference Documents: FM-22 = Generic Set-Up Manual template
 GI-Q2 = Inspection Procedure for a Production Run
 FQ-18 = Set-Up Manual Sign Out Log

Procedure:

1. Regarding a new job start-up and Process Design, it’s necessary for all vital set-up parameters to be determined and documented for future reference. Production Managers may delegate this task to appropriate personnel.
2. While a new job set-up is conducted, all applicable settings, controls, and indicators must be recorded. A hard copy of form #FM22 (Generic Set-Up Manual template) can be used for this record.
3. A validation of these settings must be made through product inspection in accordance with procedure GI-Q2 “Inspection Procedure for a Production Run”. If the part quality is short of requirements, remedial adjustments should be made. Any changes deemed necessary, must be recorded on the “Set-up Manual template”.
4. When an optimum Set-up has been reached, properly documented, and Quality procedure GI-Q2 is complete, the production process can begin. The hand written Set-Up Manual can remain with the job while determining if any other changes are necessary.

Procedure Continued:

5. At such time that the Production Manager is confident the Set-up parameters are optimum, the hand written template is given to Document Control.
6. Document Control will type the information into an electronic format, print a hard copy, place it in an appropriate binder and circulate this new Set-Up Manual for 3 signatures, i.e. the Production Supervisor, Production Manager, and Quality Manager. The signatures are meant to authenticate the Set-Up Manual.
7. The electronic file will be maintained in the Document Control database for future reference and potential updates. The hard copy Set-Up manual will also be maintained in Document Control, but made readily available to production.
8. When a Set-Up Manual is needed, Production personnel can remove it from the file cabinet and record an entry on form FQ-18, (Set-Up Manual Sign Out Log). They can now take the manual and proceed with production.
9. If a change to the Set-Up Manual is deemed necessary, a hand written note can be made directly in the Set-Up Manual. This change can only be made by persons authorized by the Production Manager, and must be signed and dated by the person making the change.
10. When production is over, the manual must be returned to Document control and recorded as such on FQ-18.
11. Set-Up Manuals that have been returned to Document Control will be reviewed for changes by Quality personnel and the following actions taken.
 - If no changes were made, the Set-Up Manual is filed for future use.
 - If changes were made, the electronic file is opened, changes incorporated, and a new hard copy is printed. The newly printed hardcopy is circulated along with the old Set-Up manual for three signatures; again, authenticated by the Production Supervisor, Production Manager, and Quality Manager.
12. Once returned to Document Control, with three signatures, the old Set-Up manual is removed from the binder, replaced with the new Set-Up manual, and filed for future use.

Note #1: Changes are meant to take place expeditiously, but occasionally a Set-Up Manual is needed before the change process is complete. At the Production and Quality Manager's discretion, handwritten changes on the production floor are acceptable on limited bases.

Note #2: Set-Up Manual's are meant to ensure consistent part quality and production efficiency, but occasionally we're faced with un-controllable circumstances, (most notably raw material variations). It's imperative that we adapt to such elements and may respond with temporary deviations to the Set-Up Manual. Temporary deviations will be sanctioned by the Production Manager, and part quality must be assured by the Quality Manager.