Updating Profile Data in FACTS - Guidance

Updating Profile Data in FACTS (This information is provided by DCIQA HFC-240)

Profile data must be updated in FACTS to establish or update a firm's profile information. This should be done by the investigator in the preparation of the inspection record in FACTS before setting it to "awaiting endorsement" or, in the case of a potential OAI inspection, as soon as the investigator and supervisor concur that there is a reasonable probability that the inspection might result in an OAI recommendation. An FI status (further action indicated) for a potential OAI should be entered into FACTS while the inspection is ongoing. (Note: an ad hoc compliance assignment can be created at the same time a profile is set to "FI.")

The FACTS investigator role:

For Domestic Inspections:

The investigator enters an “Initial” status of "AC” in the Profile Status field for inspections classified as NAI or VAI.

The investigator enters an "Initial" status of "FI" immediately upon determining that the inspection has the potential to be classified as OAI.

(**Note:** For domestic inspections, it is no longer necessary to send hardcopy or e-mail documentation of Potential OAI Notifications to HFC-240).

For Foreign Inspections:

When a potential OAI inspection cannot immediately be entered in the FACTS firm profile record for a foreign firm, the investigator should notify the Division of Field Investigations (DFI) of the potential OAI situation via FAX (301-827-6685 or 301-443-6919) as soon as the potential OAI situation is known and during his investigation. DFI will forward the OAI notification to the appropriate Center and to DCIQA (HFC-240) at 240-632-6824 or by e-mail to ORA HQ DCIQA Employees.

Foreign Preapproval Inspections:

When the preapproval inspection is the initial (1st) inspection of the firm (*no previous inspection record exist in FACTS*) and the inspection is found to be OAI (unacceptable), the investigator should not enter profile information but instead should uncheck the ProReq (profile required) box on the Maintain Inspection Results screen.

NOTE: For all Device inspections (foreign and domestic) record all applicable profiles for the establishment as having been covered if the inspection was at a minimum a Level 1, Abbreviated Inspection (QSIT).

For all drug inspections made utilizing the top-down systems approach, the same will apply.

The FACTS IB supervisor role:

For Domestic Inspections:

In the case of a NAI or VAI inspection the supervisor will set the "Record Final" status to "AC" on the profile screen when endorsing the inspection in FACTS.

In the case of a potential OAI inspection the supervisor adds, "Refer to Compliance (with date)" in the "Record Initial" Remarks field before sending the inspection to compliance.

For Foreign Inspections:

The supervisor verifies that the investigator has properly completed his/her role and will enter “Refer to Center Compliance" (with date) in the “Record Initial" Remarks field on the profile screen.

Center compliance sets the "Record in Review" status, for all foreign inspections, when they receive the EIR and "Record Final" status when they finish their review. The Remarks field of the “Record in Review” line should be updated whenever any significant steps are made in the review process.

The district does not enter a "Final" status for any profile class for any foreign inspection.

For Biologics Core Team OAI Inspections (Foreign and Domestic):

The Team’s compliance officers in OE will set the "Record in Review" status when they receive the EIR and "Record Final" status when they finish their review and consultations with CBER. The Remarks field of the “Record in Review” line should be updated whenever any significant steps are made in the review process.

The District Compliance role:

For domestic potential OAI inspections, the compliance officer sets the FACTS firm record to “Record in Review” as soon as the inspection is submitted to compliance branch for evaluation.

The compliance officer uses the Remarks field of the Maintain Profile screen to keep track of the progress of the review. If the action is submitted to a center or counsel for further review or opinion, the compliance officer will annotate this in the Remarks field and include the date it is submitted.

When a final decision has been made, the compliance officer closes the inspection in Final with the district’s decision. If the final decision results in an action being taken, the Remarks field will be annotated with the type and date of the action taken.

Center Compliance role:

Foreign inspections

The Center compliance officer reviews **all** foreign inspections and enters the Final profile status on the Maintain Profile screen.

Center compliance sets the "Record in Review" status when they receive the EIR before starting their review and will enter a "Record Final" status when they finish their review and have reached a final conclusion. The Remarks field of the “Record in Review” line should be updated whenever any significant steps are made in the review process.

Foreign pre-approval inspections:

If, after review of an initial pre-approval inspection *(1st inspection of the firm)* which was found to be violative by

the district and not profiled, center compliance decides the GMP deficiencies are not sufficient enough to warrant non-approval, the center compliance officer must notify the investigator so that the “Record Initial” profile information can be entered.

Profile Process

1. Prior to the inspection, the investigator should review the firm's profile history in the FACTS Firm Profile Record and make a copy to take with him/her on the inspection to assure that all profile class codes will be addressed during the inspection including unacceptable profile statuses or other negative information.
2. When performing a top-down, systems-type inspection for drugs and medical devices **all** profile classes applicable to the establishment and its products can be considered to have been covered by the inspection.
3. Add any "new" profile classes.
4. Include the last date of the inspection and the compliance status. Use the Remarks field to clarify information such as regulatory action taken or recommended and the date of such actions.
5. When a firm no longer manufactures products in a listed profile class, discontinue those class(es) in the profile record of FACTS using the **Discontinue** button. When a wrong profile class code has been entered, it can be deleted by the investigator using the **Delete** button on the profile screen if the information has not been saved. However, once it is saved, it cannot be deleted by the investigator. Contact DCIQA (HFC-240) to delete if this occurs. **Do not use the Discontinue function to delete an error.**
6. When profile classes BMI, NEC, SOL, or MIS are used to identify product(s) not elsewhere classified, be sure to use the Remarks field on the profile screen to identify the product(s).
7. Make name and/or address changes using FACTS Firm Maintenance.
8. When a firm is doing business under a different name, use FACTS Firm Maintenance to list DBA's.
9. When reporting information into FACTS, if a firm is considered to be unacceptable by a District (or in the case of a foreign inspection, by a Center), any regulatory action recommended, and the date of the recommendation, must be noted in the Remarks field of the “Record in Review" line on the Maintain Profile screen. The same is true for the "Record Final." The Remarks field must include any regulatory action taken and the date. The Remarks field should be updated accordingly as the potential compliance action travels through the compliance subsystem of FACTS.
10. If the deficiencies are product(s) specific, within a profile class, and the overall profile class status is considered acceptable, record AC for profile status in "Record Initial" and UN (unacceptable) in "Remarks Status" for the product specific item. Use the Remarks field to record the reason for the product-specific status and include the product(s) when possible or the statement “contact center (or district) for specific products.” Compliance, after their review, will either concur with the initial product-specific unacceptable status, or change it to acceptable when entering a "Record Final" status. The Remarks field should be used by compliance to explain any reversal in thinking from what the investigator entered.
11. When a profiled firm goes out of business, changes operations, or discontinues production of FDA regulated products, record the appropriate information on the FACTS Maintain Firms screen and remember to remove the profile required flag.
12. Update Operation type from the drop down menu.
    a. For devices: If a firm manufactures sterile products, include the appropriate sterilization profile class code(s) along with the profile class codes of the products manufactured. In the Remarks field of the Maintain Profiles screen, under Current Profile Status, state whether the sterilization is performed "on-site” or "off-site". For off-site sterilization, (*which includes sterilization done by a division of the same firm*), include the name of the sterilizer, city, state/country and FEI (optional) in Remarks.
    b. If a firm is a contract sterilizer only, use the appropriate sterilization profile class code, and from the Operation Type drop down menu, choose "Contract Sterilizer Only."
    c. If a firm is a control testing laboratory only, use the CTL profile class code (listed under Devices-*irregardless of the type of products tested)* and from the "Operation Type" drop down menu, choose "Control Testing Lab Only."
        i. If a firm is a control-testing laboratory for its’ own products - do not use CTL.
        ii. If the firm does validation, stability, etc., work for other firms, use the appropriate testing lab profile class code, i.e., CTB (Biologics), CTD (Devices) or CTX (Drugs) and, from the "Operation Type" drop down menu, choose "Control Testing Lab Also."
13. For profiling purposes, the inspection date entered in the "Date" field of Current Profile Status on the Maintain Profile screen is the last date of the inspection entered in the EI record. The Status Date is the date the inspection information was entered. The Status Date is part of the audit trail and should not be backdated or changed.
14. When to use “Others” as found on the Profile Status (Final) drop down menu:
    a. Consent Decree - When a firm is operating under a consent decree the final profile status will be "Others." The Remarks Status field should reflect the status of the current inspection (Acceptable or Unacceptable). The Remarks field must state that the firm is operating under a consent decree; products are approved on a product-by-product basis. The Remarks field should also provide information on the current inspection (i.e., if the current inspection is Unacceptable list the type of regulatory action taken and the date of the action.) The consent decree information should be carried forward to each new inspection until it is lifted at which time the Remarks field should be used to

record “consent decree lifted” and the date it was lifted.

b. Application Integrity Policy - When a firm is operating under an Application Integrity Policy (AIP) the Final profile status will be "Others." The Remarks Status field should reflect the status of the current inspection (Acceptable or Unacceptable). The Remarks field must state that the firm is operating under an AIP and that the products are approved on a product-by-product basis. If feasible list the product(s) under AIP **or** include the statement “contact the district or center for list of products.” The AIP information should be carried forward to each new inspection until it is removed at which time the Remarks field should be used to record “AIP removed” and the date of removal.

NOTE: The GMP "Last Final Status" field [top portion of profile screen-Profile Classes] should always be OT for firms under a Consent Decree or Application Integrity Policy. Setting the Profile Status (in Final) to "Others" will accomplish this.

NOTE: Although "Others" is typically used for firms operating under a Consent Decree or Application Integrity Policy, certain special circumstances may warrant the use of "Others" as a final profile class code. If you have questions or would like to discuss the circumstance in which "Others" may be used, please contact DCIQA (240-632-6820) or visit the DCIQA website for additional information.

15. There are times when the district or center’s course of action for an OAI inspection is not to immediately issue a warning letter or take regulatory action, but instead seek compliance via an alternative means, such as a reinspection.

    For these cases, the profile status for the OAI inspection should not be finalized. Instead, the compliance officer should enter the “Record in Review” as “Pending” and track the action in the “Remarks” field.

    After the re-inspection, the investigator must **uncheck** the ProRqd box on the Maintain Inspection Results screen before entering the information for the reinspection.

    Unchecking the ProRqd box avoids the “normal requirement” to update the firm’s profile(s) for the reinspection.

    If this reinspection continues to be OAI, the investigator should note in the Remarks field on the Maintain Inspection Results screen “referred to compliance” and include the date.

    The compliance officer has the responsibility to update the firm’s profiles (via the original inspection record) by updating the Remarks field in the “Record in Review,” and recording all recommendations, etc. The Record in Review “Pending” status can remain open for as long as is required and can (and should) be edited repeatedly, until a final decision is made.

    When a final decision is made, Compliance should access the original Maintain Profile Screen through the original Maintain Inspection Results screen and enter the firm’s “Final” profile status of AC or UN (if UN, an action and date must be recorded in the Remarks field.)

16. After a final district decision is entered in the FACTS Maintain Inspection Results screen and before setting the record to Completed, the supervisor or compliance officer should remember to enter the Final Status for each profile class code in the Maintain Profiles screen.
17. When merging firms in FACTS you should not attempt to merge two firms when either of those firms have any profile class codes which have not been entered in “Final”. Merging firms that have profile classes left in “Initial” or “Pending” status causes a FACTS error that will not permit entering the “Final” status without changes or repairs. Merging should be done only by authorized district FACTS personnel.
18. When to use profile status codes HO (hold) and PN (pending):
    a. PN - Compliance work is being done on the item. Use for all work sent to Compliance. Remarks should be updated to reflect overall status, action, and action status.
    b. HO - Used for a number of reasons that cause any compliance component to stop work on the item, e.g., awaiting policy decisions, temporary abeyance, etc.

Establishment Profile Criteria

Profile the following device, biologic, human and veterinary drug establishments:

Manufacturer - Makes a new or a changed product from one or more ingredients.

Remanufacturer **-** A person who processes, conditions, renovates, repackages, restores, or performs any other act to a finished device that significantly changes the device's performance or safety specifications or intended use.

Reprocessor **-** A person who performs remanufacturing operations on a single-use device.

Packer/ Repacker **-** The establishment packs a product or products into different containers without making any changes in the form of the product.

Labeler/ Relabeler **-** An establishment which affixes the original labeling to a product or changes in any way the labeling on a product without affecting the product or its container.

Contract Sterilizers **-** Performs sterilization or irradiation of products or components of products regulated by FDA on a contract basis.

Control Testing Laboratories **-** Performs production quality control work related to products regulated by FDA on a contract basis.

Assemblers of Medical Device Kits **-** Person or establishment responsible for assembling finished devices into medical device kits.

Tissue Establishments **-** Only tissue establishments inspected as device firms under the Quality System regulations or regulated as biological products

Specification Developer **-** A person who initiates or develops specifications for a device that is distributed under the establishment's own name but is manufactured by a second person.

The following establishment and operation types are not profiled.

Blood Banks
Methadone Clinics
Manufacturers of "Research Use Only" Products
Pharmacies and Retail firms
Distributors
Plasmapheresis Centers
Custom Device Manufacturers
Veterinary Medical Device Firms
X-ray Assemblers
Mammography Clinics
Manufacturers of General Purpose Articles (Devices)
Physicians Offices, Hospitals and Clinics
Laser Light Shows/Television and Microwave Oven Manufacturers
Sun tanning Establishments
Device Component Manufacturers
Clinical Investigators/Bioresearch Monitoring
Tissue firms inspected under Good Tissue Practices
Any Non-GMP Inspection

For more information contact your District Profile Coordinator, DCIQA (240-632-6820) or the DCIQA web page.

Profile Class Codes with Definitions

Note: These are the profile codes *as they appear* in the FACTS drop down menu.

For more information contact your District Profile Coordinator or DCIQA at 240-632-6820.

BIOLOGICS

Profile Code(s)	Definitions
AEV	ANTITOXINS, ANTIVENINS, ENZYMES, AND VENOMS
AFP	ANIMAL DERIVED FRACTIONATION PRODUCTS
ALP	ALLERGENIC PRODUCTS
BGR	BLOOD GROUPING REAGENTS
BMI	BIOLOGICAL PRODUCTS NOT OTHERWISE CLASSIFIED (LAL, BLOOD COLLECTION BAGS WITH ANTI-COAGULANT, ETC.) **(NOTE SPECIFIC PRODUCT(S) IN REMARKS)**
BTP	BIOLOGICAL THERAPEUTIC PRODUCTS
CBS	COMPUTER BIOLOGICAL SOFTWARE
CTB	CONTROL TESTING LABORATORY "ALSO" (BIOLOGICS)
HFP	HUMAN DERIVED FRACTIONATION PRODUCTS
SMC	SOMATIC CELLULAR PRODUCTS
TIS	HUMAN TISSUE REGULATED BY FDA
TOX	TOXOIDS/TOXINS
TRP	THERAPEUTIC RECOMBINANT PRODUCTS
VBP	VACCINE BULK PRODUCT
VFP	VACCINE FINISHED PRODUCT
VIV	IN VIVO DIAGNOSTICS
VTK	VIRAL MARKER TEST KIT

DEVICES

Profile Code(s)	Definitions
BBP	BLOOD AND BLOOD PRODUCTS UNLICENSED
CCR	CLINICAL CHEMISTRY REAGENTS (INCLUDES DIAGNOSTIC TAPES, STICKS, ETC.)
COH	COMPUTER HARDWARE
COS	COMPUTER SOFTWARE (DEVICE ONLY)
CSP	CHEMICAL STERILIZATION
CTD	CONTROL TESTING LABORATORIES "ALSO" (DEVICE)
DKA	DEVICE KIT ASSEMBLER
ELE	ELECTRICAL ASSEMBLY
FSP	FILTRATION STERILIZATION
GLA	GLASS OR CERAMIC FABRICATION AND ASSEMBLY
GSP	GAS (ETO, PROPYLENE OXIDE STERILIZATION)
HCP	HEMATOLOGY AND COAGULATION PRODUCTS
HSP	DRY HEAT STERILIZATION
HTD	HUMAN TISSUE DEVICE
MED	MEDIA (INCLUDES MICROBIOLOGICAL AND TISSUE CULTURE, GROWTH MEDIA AND ACCESSORIES, INCLUDING INGREDIENTS)
MIS	NOT ELSEWHERE CLASSIFIED **(NOTE SPECIFIC PRODUCT(S) IN REMARKS)**
MTL	METAL FABRICATION AND ASSEMBLY
OPT	OPTIC FABRICATION AND ASSEMBLY

Profile Code(s)	Definitions
	(CONTACT AND OTHER LENSES, EYEGLASS, ETC.)
PBM	PROCESSED BIOLOGIC MATERIAL
PRF	PLASTIC OR RUBBER FABRICATION AND ASSEMBLY
RIP	RADIOIMMUNOASSAY PRODUCTS
RSP	RADIATION STERILIZATION
SIP	SEROLOGICAL AND IMMUNOLOGICAL PRODUCTS (INCLUDES BACTERIAL TYPING, RHEUMATOID FACTORS, PREGNANCY KITS, IVD OTHER THAN VIRAL MARKER TEST KITS, ETC.)
SOL	DEVICE SOLUTIONS AND GELS (INCLUDES CONTACT GELS, DIALYSIS SOLUTIONS, DENTAL PASTES, ADHESIVES, ETC.)
SSP	STEAM STERILIZATION
SPD	SPECIFICATION DEVELOPERS
TSP	FRACTIONAL TYNDALLIZATION STERILIZATION
TXT	TEXTILE FABRICATION AND ASSEMBLY
WOD	WOOD FABRICATION AND ASSEMBLY
WSP	WATER STERILIZATION

DRUGS

Profile Code(s)	Definitions
ADM	AEROSOL DISPENSED MEDICATION
CBI	BIOTECHNOLOGY CRUDE DRUGS
CEX	PLANT/ANIMAL EXTRACTION CRUDE DRUG
CFN	NON-STERILE BULK BY FERMENTATION CRUDE DRUGS
CFS	STERILE BULK BY FERMENTATION CRUDE DRUGS
CHG	CAPSULES, PROMPT RELEASE
CRU	CRUDE BULK DRUGS (NON-SYNTHESIZED)
CSG	CAPSULES, SOFT GELATIN
CSN	NON-STERILE BULK BY CHEMICAL SYNTHESIS
CSS	STERILE BULK BY CHEMICAL SYNTHESIS
CTR	CAPSULES, MODIFIED RELEASE
CTX	CONTROL TESTING LABORATORIES "ALSO" (DRUGS)
GAS	MEDICAL GAS (INCLUDES LIQUID OXYGEN)
LIQ	LIQUIDS (INCLUDES SOLUTIONS, SUSPENSIONS, ELIXIRS, TINCTURES, ETC.)
LVP	LARGE VOLUME PARENTERALS
NEC	NOT ELSEWHERE CLASSIFIED (**NOTE THE SPECIFIC PRODUCT(S) IN REMARKS)**
OIN	OINTMENTS, NON-STERILE (INCLUDES CREAMS, JELLY, PASTE, ETC.)
POW	POWDERS (INCLUDES ORAL AND TOPICAL)
SNI	STERILE NON-INJECTABLE
SUP	SUPPOSITORIES
SVL	SMALL VOLUME PARENTERALS (LYOPHILIZED)
SVS	STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS
SVT	TERMINALLY STERILIZED SMALL VOLUME PARENTERALS
TCM	TABLETS, PROMPT RELEASE
TCT	TABLETS, DELAYED RELEASE
TDP	TRANSDERMAL PATCHES
TTR	TABLETS, EXTENDED RELEASE
	NOTE: CCS and SVP are no longer used.

MISCELLANEOUS

Profile Code(s)	Definitions
CTL	CONTROL TESTING LABORATORIES "ONLY" (NO MANUFACTURING DONE ON SITE)

VETERINARY PRODUCTS

Profile Code(s)	Definitions
IMN	IMPLANT NON-STERILE
IMS	IMPLANT STERILE
TAM	TYPE A MEDICATED ARTICLE