



DEPARTMENT OF HEALTH AND  
HUMAN SERVICES

Public Health Service  
Food and Drug  
Administration

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**Memorandum**

Date: September 20, 2010 **updated September 28, 2010**

From: Consumer Safety Officer, Division of Field Programs and Guidance, OC

Thru: Team Leader, Field Programs Branch, HFS-615

Subject: Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule,  
FPG Assignment # 10-29, ORA Concurrence # 2010092001  
FACTS No. 1209037

**Freedom Of Information Act Version (FOIA)**

To: DIBs  
District Food Team Leaders:

Info: RFDDs  
DDs

**Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.**

**Background**

On July 9, 2009, the Agency published in the Federal Register a final rule entitled Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation, and Storage (74 FR 33030)( <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170746.htm> ) (hereinafter referred to as the Egg Rule).

In July 2010, producers with greater than 50,000 or more laying hens became subject to the Egg Rule. The Egg Rule requires that shell egg producers implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with the FDA.

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USDA/AMS, a federal partner in shell egg oversight, understands FDA's inspectional approach from a national perspective. During inspections, FDA investigators, and state regulatory partners accompanying FDA or performing inspections under FDA contract, will contact any USDA/AMS inspectors on site.

## **Objectives**

- **To inspect establishments to assess compliance with 21 CFR 118:(Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation Rule) to include:**
  - **Evaluation of the SE prevention plan**
  - **Evaluation of the egg laying operation**
  - **Evaluation of firm's environmental testing and appropriate actions taken if a positive sample was found**
  - **Record review**
- **To conduct environmental sampling and inspections at egg laying farms to determine if the firm is practicing prevention measures of Salmonella Enteritidis contamination of the egg and egg production areas;**
- **To conduct laboratory analyses of environmental samples**
- **To document inspectional and analytical findings and initiate compliance action as warranted**

## **Inspectional Approach**

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Conduct inspections of the egg production facilities of each firm listed (#) Inspections are to be conducted with a team of Investigators. A minimum of 3 investigators are needed per team, 5 are preferable, especially for larger facilities. Lead Investigators must have attended DHRD course FD107 in July with follow-up webinar in September or subsequent FD107 courses. The course training manual provides specific instructions for how to conduct these inspections.

ORA (DDFI/DFS) will provide a master tracking schedule indicating the week of the inspections for districts and analyzing laboratories. This will be included as a separate attachment sent with the assignment. Pullet houses are not to be inspected or sampled as part of this assignment.

Inspections under this assignment are to minimally include the following components:

- Evaluate the SE prevention plan
  - Procurement of pullets that are SE monitored
  - Biosecurity measures
  - Rodent/Pest control measures
  - Cleaning and disinfecting measures
  - Adequate refrigeration of shell eggs

NOTE: If there is no written plan, determine if preventative controls are in place. Lack of a written SE prevention plan is a significant deviation from the Egg Rule and must be noted on the FDA 483. (See Regulatory Follow-up for other significant deviations.)

- Determine if the environmental testing and appropriate actions were taken, accordance with the rule , if a positive sample was found
- Determine if the plan has been implemented
- Review records (monitoring, sanitation)
- Determine if the SE prevention measures are being practiced
- Conduct environmental sampling
- Verify the firm’s registration
- Issue an FDA-483 to cover any significant objectionable conditions observed during the inspection and prepare the EIR in accordance with established procedures.

(#) is an inspectional tool to help guide the Investigator through the inspection. It provides useful citations to Part 118 of the regulation, covers questions and areas of significance, and will help the Investigator to prepare the FDA-483. When completed it must be inserted into the EIR under the heading, “Additional Information”. This tool will form a significant portion of the EIR. **If during the course of the inspection, significant objectionable conditions are observed that raise concerns about potential SE contamination and egg safety, contact the ORA DDFI inspection contact to initiate a strategy discussion with CFSAN, ORO and OE.**

If a farm also has an egg-breaking facility on-site, that aspect of their operations is under USDA jurisdiction and will not be inspected by FDA. Some farms with an egg packing facility will be under contract with USDA/AMS for egg grading. Such farms are also evaluated by USDA/AMS for sanitation. During inspections, FDA investigators, and state regulatory partners accompanying FDA or performing inspections under FDA contract, will touch base with any USDA inspectors on site. The packing facility will not routinely be covered during this assignment.

## **Biosecurity/Personal Protection Requirements**

**Egg farm inspections require unique action by Investigators to assure that we do not contaminate or cross-contaminate the environment. Additionally, our investigators must take steps for their personal safety. The following are requirements:**

- The Investigator must be respirator fitted and certified. Respirator must be sanitized between houses.
- The Investigator must not be a bird and/or reptile owner in their own home and/or must not have been in any other poultry/reptile facility up to 72 hours before an inspection, including visits to aviaries, tending backyard feeders, etc.
- Disposable personal protective clothing (e.g., Tyvek<sup>®</sup> suits, booties, gloves) must be changed between poultry houses on the farm to avoid any potential for cross-contamination of not just SE but other infectious bird diseases such as avian influenza (AI) and exotic Newcastle disease (END).

- Vehicles to be used for transport to egg farms are required to be cleaned and the tires disinfected prior to arrival at the farm. After leaving the farm location the vehicle must be cleaned, including the car, tires and wheel wells, at a car wash. Tires must again be disinfected with 70% ethanol or a bleach solution.
- Photographs should be obtained, if possible. Use separate disposable cameras for each house. **NO FLASH should be used at any time, so as not to frighten the birds.**
- Unless mandated otherwise by the farm's Biosecurity procedures, Investigators must take and properly dispose of any waste generated during egg farm inspections. To avoid cross contamination of the interior of vehicles, waste and supplies must be sanitized or bagged before touching the interior of the vehicle
- Because the nature of the work and the wearing of Tyvek<sup>®</sup> suits and respirators can be tiring and warm, the team should dress appropriately and bring a supply of water, energy drinks, and snacks. Coolers for this use should be clearly identified to ensure that there is no cross contamination with sample coolers.
- Before conducting the inspection, a member of the team should be designated as the team safety officer and be familiar with Biosecurity and Personal Protective Equipment (PPE) requirements to help support the safety of all team members.

**Movement between houses should be inspected from the youngest birds to the oldest birds. Houses and birds known to have diseases, including SE, should be visited last.**

**Any additional questions or concerns regarding Biosecurity/PPE should be directed to CDR. Michelle Markley, 301-796-8178.**

### **Involvement of State Regulatory Partners**

**Prior to conducting the inspection, the District must contact the State Program Contact (#) to determine if there is a state quarantine or other prohibition from entering the farm. Document that this inquiry was made in the EIR.**

Prior to planning inspections, consult with the appropriate state regulatory agency contact as identified in Attachment C regarding the inspections and request that the state accompany FDA on all inspections (even if they have not attended the FDA/DHRD Egg Rule Training Course). Refer to (#) for a list of state officials that currently have responsibility for egg laying operations

Provide the State Program Contact with a copy of this assignment and refer to the Biosecurity/PPE requirements. The State representative participating in the inspection will need to comply with the Biosecurity and Personal Protection requirements as indicated above, except that State personnel may follow their State requirements for respiratory protection. A minimum of an N-95 type mask is strongly advised. Should the State Agency have questions regarding obtaining the required PPE, they are directed to contact the local FDA District Office.

After the inspections conclude, keep involved state officials informed of any possible compliance actions.

## **Environmental Sample Collection**

Environmental samples in the hen houses will be collected during the inspections under this assignment to assess conditions and obtain baseline information about the state of the industry.

Egg farms can have multiple physical locations (sites with different addresses), which can contain a number of separate henhouses. In order to assess the conditions in a representative manner, determine the number of hen houses per egg laying site that will be environmentally sampled as follows:

- If there are (#) houses at the site, the Investigator should collect environmental samples at all of the houses on site.
- If there are (#) houses at the site, the Investigator should select (#) houses from which to collect environmental samples. In this case, the houses should be prioritized based on observations, the firm's sample records and sample schedule, etc.

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### ***Sampling Technique:***

**Drag swabs of manure are the preferred environmental sample (water, feed or egg samples are NOT to be collected as part of this surveillance assignment). Detailed instructions are available at the following two websites:**

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm222469.htm>

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm>

**The following information includes swab type and preparation, assembling/use of a drag swab, and sampling approaches depending on the farm's approach to manure management.**

#### **a. Swab Type**

4x4, 12 ply sterile gauze pad with string (manure samples) – drag swab

4x4, 12 ply sterile gauze pad without string (for egg belt samples) – hand swab

#### **b. Swab Prep**

When the swabs are ready to be used, the investigator must aseptically moisten them with canned evaporated milk (investigator should use evaporated milk from the same lot for each house). Multiple cans/vials may be needed with the same lot codes preferred. Sanitize the tops of the milk cans prior to opening with a 70% ethanol solution. Control samples of the milk will be submitted with the sample.

#### **c. Drag Swab Assembly**

Assembly of a drag swab will assist in collection. Districts should purchase metal poles, suitable for sanitation (stainless steel preferred). The moistened drag swab with string should be aseptically and securely tied to the metal pole. The metal pole must be thoroughly sanitized between houses.

#### d. Sample Collection Method

For the purposes of this section:

*Row* means a group of cages that runs the length of a house.

*Bank* means half of a cage row (one side of a row – left or right).

*Tier* means a level of cages in each row.

Manure is the preferred sample type. Use a 4 in x 4 in, 12 ply sterile gauze pad which is aseptically attached to a drag pole, which should be disinfected before each use with 70% ethanol. Drag the moistened gauze pad over the manure the entire length of one side of the row/bank. Take another gauze pad and drag the other side of the row/bank. Repeat this procedure on all rows/banks of the house.

Place each pad in a separate Whirl-Pak<sup>®</sup>-type bag with sufficient milk to keep the pad wet (no more than a tablespoon or approximately 15 ml).

#### Manure Management - Shallow Pit

Most shallow pit operations have some type of manure scraper. Some have scrapers under each tier, some have a floor scraper only, and some have a combination of both. In these operations, each scraper blade should be swabbed. Only the solid manure on the scrapers should be sampled, as ammonia in the pit liquid may inhibit SE growth. (If the manure in the pit is dry, drag swab the pit as outlined above.) Sampling can take place either while the scraper is running or while it is stationary.

##### *When scraper is running*

Attach two drag swabs onto the manure scraper assembly and run the scraper to the opposite side of the house. Remove the swabs and place them into appropriately labeled Whirl-Pak<sup>®</sup> bags (one swab per bag).

##### *When scraper is stationary*

Use two swabs to hand-swab the solid manure on all scraper blades on each bank and place into separate appropriately labeled Whirl-Pak<sup>®</sup> bags (one swab per bag). If the shallow pit has a narrow walkway beneath it, use a drag pole to take swab samples underneath the row of cages, and place swabs into appropriately labeled Whirl-Pak<sup>®</sup> bags (one swab per bag).

#### Manure Management - Belt System

Hand-swab each of the upper belts/scrapers for each bank with one swab and place that swab in a labeled Whirl-Pak<sup>®</sup> bag. Repeat for the lower belts/scrapers. Take separate subs from manure belts and scrapers on each cage level at the end of each cage row. Sampling should be from left to right when facing the back of the house. Each swab should be placed in a separate Whirl-Pak<sup>®</sup> bag.

### Manure Management -- Pits Unsuitable for Drag Swabbing

If Investigators encounter manure pits that are unsuitable for drag or hand swabbing – that is, manure that is piled very high or is liquid or semi-liquid – as an alternative, representative egg belt environmental sampling and walkway environmental sampling will be conducted.

Egg belts: Hand-swab the egg belts (swab approximately 10-12 feet per belt on each cage level) and the de-escalators on each level for each bank of cages. Use a separate swab for each egg belt (including de-escalators) for each side of the bank. Place each swab into its own Whirl-Pak<sup>®</sup> bag. Continue with this procedure from for all cage rows.

Walkways: Drag two swabs along the length of each walkway. Place each swab into its own Whirl-Pak<sup>®</sup> bag.

### Manure Management -- Cage-free Operations

The following number of swabs should be collected per house, based on the width of the house, as follows:

55 or more feet wide = 12 swabs

46 – 54 feet wide = 10 swabs

37 – 45 feet wide = 8 swabs

28 – 36 feet wide = 6 swabs

Divide the house in half and swab each half of the house with half the number of swabs required. Use drag swab poles with multiple drag swabs on a pole, up to a maximum of 3 drag swabs per pole at one time. Swab the litter and slat area the full length of the house.

If a house has multiple floors, divide the number of swabs evenly to cover each floor equally. Place each swab in a separate Whirl-Pak bag.

### *Sample Numbering System*

Samples collected in one house in one day will have a unique sample number with the requisite number of subsamples. To promote consistency and understanding of the results, a specific subsample identification system is recommended, with examples as follows:

Manure:

3 L M

3 = Row number

L = Left side of the bank

For the right side of a bank use the letter R

M = Manure

Egg belt:

1 R 3

1 = Row number

R = Right side of the bank

For the left side of a bank use the letter L

3 = Tier number (if multi-tiered house)

Walkway:

2 L W

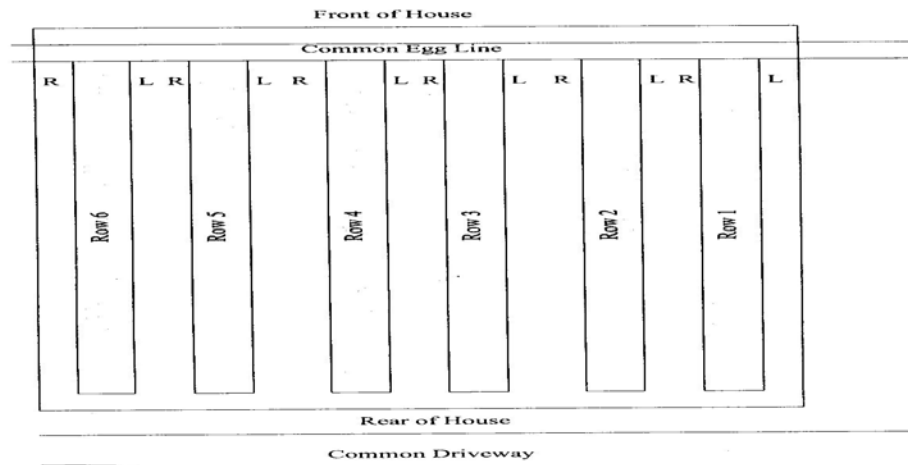
2 = Walkway/aisle number

L = Left side of bank

For the right side of a bank use the letter R

W = walkway

Figure 1: Diagram of typical egg house



**Note: As stated above, do not collect both manure and egg belt/walkway samples. Collection of egg belt and walkway samples is to be done only when the manure is inaccessible.**

### Sample Shipment

The Districts will arrange sample shipment to the servicing laboratories (#)

The NSD will NOT be utilized for this assignment. Districts should keep servicing laboratories informed of sample shipments. Samples should be sent at the end of each day collected via UPS Next Day Air Early AM delivery



Samples should be shipped so that they arrive in the laboratory Monday through Thursday. Special arrangements between the district and servicing laboratory will need to be made for any other situations. Ship samples in an insulated transport container under refrigerated conditions to keep the samples cold, but not frozen, to microbiology field laboratory for analysis within 24 hours. If samples cannot be processed immediately, refrigerate at 42°C (39.2°F). Start sample analysis within 48 ±2h of collection.

### **Analytical Instructions:**

Analyzing laboratories: (%)

Sample Analysis - Analyze environmental samples for SE (SE) according to the following methods:

SE- Isolation/Identification:

Use method entitled “Environmental Sampling and Detection of Salmonella in Poultry Houses,” October 2008. This method is available at the following website:

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/ucm114716.htm>

SE- Identification/Speciation:

Bacteriological Analytical Manual (BAM) Online: Chapter 5

<http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/UCM070149>

### **Regulatory Follow-up**

FDA’s Egg Rule enforcement authority is established under the Public Health Service Act (the PHS Act), as well as the Food, Drug and Cosmetic Act (the Act). As such, the failure to adequately implement the provisions of the Egg Rule is a violation of 42 U.S.C. 264(a) and the implementing regulation in 21 CFR 118 (the Egg Rule). In addition, significant violations of the Egg Rule render the eggs adulterated within the meaning of 402(a)(4) of the Act.

**If an inspection results in FDA positive SE environmental samples, the district should first inform the State regulatory agency of the findings. FDA and the State should jointly contact the firm immediately following the State notification. Per FMD-147, positive results should also be shared with the firm in writing.**

**The State regulatory agency (FDA Commissioned Officer) should be informed immediately of any significant findings leading to possible enforcement actions and irrespective of the inspection findings. A copy of the EIR should be provided to the FDA Commissioned Officer in that Agency upon completion. If the recipient is not commissioned, redaction may be needed.**

Districts should recommend Warning Letters to CFSAN for egg producers with significant deviations from the egg rule. All violations must be documented on the FDA 483 and discussed with firm management.

Significant deviations from the Egg Rule include:

- Lack of a written SE (SE) prevention plan or significant requirements not included such as:;
  - Failure to procure pullets that are SE-monitored
  - Failure to include Biosecurity measures
  - Failure to include Rodent/Pest control measures
  - Failure to include measures for cleaning and disinfecting the poultry house
  - Failure to include measures for adequately refrigerating shell eggs
- Failure to environmentally test for SE during required time periods;
- Failure to divert eggs or begin egg testing after a positive environmental sample (sample must have been taken during required time period);
- Failure to implement the SE prevention plan;
- Failure to maintain required records documenting the implementation of the SE prevention plan; and
- Failure to monitor conditions required for implementation of the SE prevention plan.

Regulatory recommendations regarding a firm with any of the above deviations must be submitted to the Division of Enforcement via electronic copy (e.g., doc, pdf files, etc.) via the “Mission Accomplishment and Regulatory Compliance Services-Compliance Management Services” (MARCS-CMS) link located on Inside FDA’s IT Application Page under ORA Applications.

If the following scenarios are encountered during an inspection, prior to inspectional closeout, you should notify CFSAN’s regulatory contacts to discuss the need for an Order of Diversion:

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If the only significant violation noted is failure to register as required by 21 CFR 118.11(a), districts should send a direct-reference untitled letter to the firm.

Specimen charge:

The article is in violation of Public Health Services Act, Title 42 U.S.C. Section 264(a), and the implementing regulation codified in 21 CFR 118.

The article is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 342(a)(4)] because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

## Timeframes

This assignment is **High Priority** and should begin upon receipt under the aforementioned schedule of inspections (#). Please contact Norm Fogg, DDFI, if there are any needed deviations from the schedule of inspections. (#). If a regulatory action is indicated based on the investigational and analytical findings, the district should adhere to established timeframes for submitting reports and recommending action to CFSAN.

## Resources and Data Reporting

### Reporting Inspections

Egg laying farms in all Egg Rule related assignments must have the “Safety Alert” indication in FACTS/Firm Manager set to “yes” to indicate that personal protective equipment is required to be used to prevent introduction, transfer and cross contamination of *Salmonella Enteritidis* among poultry houses.

- PAC 03F836 Egg Farm Inspection/Environmental Sampling Assignment for FY10.

Note (1): Resources for these Inspections should be taken from the crab meat environmental sampling assignment (that was not issued) which are planned under 03F830

An inspectional tool (#) should be used to collect information on the inspection as a different method of data collection in order to shorten the total inspectional and reporting time burden to complete an inspection.

The TURBO EIR sites may not be available yet; therefore, the district will have to prepare their FDA 483's separate from TURBO. **Deviations from Part 118 only** are to be noted on the 483.

### Reporting Environmental Sample Collections/Analyses

**IMPORTANT:** Please remember to report all related sample numbers from related collection reports on Part 2 of the FACTS Maintain Inspection Results Screen.

### PAC 03F836 Egg Farm Inspection/Environmental Sampling Assignment

- PAF = ‘MIC’
- Sample Basis on CR = ‘Environ–Surv1’
- Product Code = 52YYY99

Note (1): Resources for sample collections/analyses should be taken from the crab meat environmental sampling assignment (that was not issued) which are planned under PAC 03F830 (CFSAN Environmental Sampling Assignments). **DO NOT REPORT ANY TIME AGAINST THIS PAC.** For this assignment, sample collections are planned with a module of 40 Hours per Operation. Note that although 31,540 Hours are planned under PAC 03F830 to conduct analyses

for all of the planned CFSAN Environmental sampling assignments, there is not a planned hours per operation module for this specific assignment.

Note (2): When environmental samples are collected over more than one day, create a new sample number/CR each day.

Note (3): The Sample Basis field on the CR (Maintain Sample Collection screen in FACTS) has been expanded to include four (4) selections as follows:

- Environ-Compl
- Environ-Survl
- Other-Compl
- Other-Survl

## CONTACTS

### **General Assignment Contact:**

Monali Yajnik OC/DFP&G/FPB, HFS-615, phone 301-436-1616,  
[monali.yajnik@fda.hhs.gov](mailto:monali.yajnik@fda.hhs.gov)

### **Regulatory Contact:**

Dwayne Johnson, OC/DE/MSAB, HFS-607, phone 301-436-1782,  
[dwayne.johnson@fda.hhs.gov](mailto:dwayne.johnson@fda.hhs.gov)

Brandon Bridgman, OC/DE/MSAB, HFS-607, phone 301-436-2073,  
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### **Environmental Sampling/Technical Contact:**

Gerardo Ramirez, OC/OFS/DPDFS/DEB HFS-316, phone 713-802-7511,  
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### **CFSAN Scientific Contact:**

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### **ORA/DFS Scientific Contacts**

Rebecca Dreisch, ORA/DFS, HFC-140, phone 301-827-9372,  
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Norma Duran, ORA/DFS, HFC-140, phone 301-827-0944,  
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### **ORA/DFSR Contact**

Ellen Laymon, ORA/ORO/DFSR, HFC-150, phone 301-827-2908,  
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### **ORA/DDFI / Scheduling Contact**

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### **ORA/DDFI Investigational Contact**

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Monali M. Yajnik

**Attachments:**

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Cc:

HFC-100 (Romano)

HFC-140 (Dreisch, Duran)

HFS-365 (Sheehan)

HFS-300 (Beru)

HFS-316 (Ramirez, Bufano)

HFS-150 (Reardon, Laymon)

HFC-130 (Fogg, Clausen)

HFS-600 (Wagner RF)

HFS-605 (Thomas)

HFS-607 (Johnson, Bridgman, Correll)

HFS-615 (Barringer, Bass, Aloï, Yajnik)