UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,250.2 | 3/2/21

PERFORMANCE STANDARDS: *SALMONELLA* VERIFICATION PROGRAM FOR RAW POULTRY PRODUCTS

I. PURPOSE

This directive provides basic information on the moving window approach for *Salmonella* sampling for raw poultry products, including FSIS sample scheduling and the subsequent categorization of performance. It also provides instructions to inspection program personnel (IPP) for reviewing the establishment's *Salmonella* control programs, and for collecting follow-up samples at establishments that do not meet (exceed) performance standards for chicken or turkey (poultry) carcasses, raw chicken parts, or not ready to eat (NRTE) comminuted poultry products. This directive also provides instructions for IPP to document a Memorandum of Interview (MOI) regarding categorization, to verify corrective actions and reassessment requirements (if applicable), and for Enforcement, Investigations, and Analysis Officers (EIAOs) to perform Public Health Risk Evaluations (PHREs) and Food Safety Assessments (FSA) when appropriate.

II. BACKGROUND

A. FSIS first established performance standards in 1996 as part of the "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems Final Rule" (61 FR 38806). Since then, it has updated the performance standards for poultry products through *Federal Register* notices.

B. As part of its *Salmonella* Verification Program, FSIS assesses whether establishments meet pathogen reduction performance standards for *Salmonella* in young chicken and turkey carcasses, raw chicken parts, and NRTE comminuted chicken and turkey products, as shown in Table 1:

Table 1. *Salmonella* Poultry Performance Standards announced in a 2016 Federal Register Notice (81 FR 7285)

Product	Performance Standard*	Maximum Acceptable Percent Positive	Minimum Number of Samples to Assess Process Control**
Broiler Carcasses	5 of 51	9.8%	11
Turkey Carcasses	4 of 56	7.1%	14
Comminuted Chicken	13 of 52	25%	10
Comminuted Turkey	7 of 52	13.5%	10
Chicken Parts	8 of 52	15.4%	10

*The performance standard is represented as a fraction of maximum allowable positives over the target number of samples collected and analyzed in a 52-week window.
**FSIS must analyze at least this number of samples in a single 52-week window in order to categorize an establishment for the standard listed.

III. PERFORMANCE CATEGORIZATION

A. As FSIS announced in the November 9, 2018 *Federal Register* (83 FR 56046), "Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Revised Categorization and Follow-Up Sampling Procedures," *Salmonella* performance standard category determinations are based on a minimum number of *Salmonella* sample results being available from a 52-week moving window. As the *Federal Register* notice outlines, the category definitions under verification sampling are as follows:

• **Category 1:** Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recently completed 52- week moving window.

• **Category 2:** Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recently completed 52-week moving window.

• **Category 3:** Establishments that have exceeded the maximum allowable percent positive during the most recently completed 52-week moving window.

B. Individual windows are defined as 52 consecutive Sunday-to-Saturday weeks. Category status is determined based on the most recently completed window.

IV. COMMUNICATING CATEGORIZATION WITH THE ESTABLISHMENT

NOTE: IPP are not to attempt to categorize an establishment by tracking FSIS's testing results. FSIS's Office of Planning, Analysis, and Risk Management (OPARM) performs and reports this analysis. Questions concerning categorization can be submitted through askFSIS.

A. When an establishment is assigned to Category 2:

1. IPP assigned to the establishment, the frontline supervisor (FLS), and the District Manager (DM), will receive an alert entitled, "Warning: Product Exceeded One Half of Performance Standard", through the PHIS dashboard. During the next weekly meeting with establishment management, IPP are to explain that the results indicate variable control of *Salmonella* and that the establishment may fail a performance standard. IPP are to advise the establishment that it may wish to make changes to avoid failing the performance standard.

2. IPP are to document notes from the meeting in an MOI in accordance with FSIS Directive 5010.1 *Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management*; and include "Product Exceeded One Half of Performance Standard" in the subject line of the MOI.

3. IPP are to ensure that the MOI documenting the weekly discussion with the establishment management follows the content and formatting guidance prescribed in Chapter IV of FSIS Directive 8010.2 *Investigative Methodology*. Specifically, the MOI:

    a. Is written in the first-person point-of-view of the FSIS employee preparing the MOI;

    b. Documents the date and location of the meeting;

    c. Documents the name and official position of the FSIS employee conducting the meeting and of any other FSIS employees present;

    d. Documents the name and official position of all establishment employees attending the meeting;

    e. Summarizes all information discussed during the meeting;

f. Includes a closing statement certifying that the MOI includes all the information discussed during the meeting; and

g. Is promptly signed and dated by the preparer upon completion.

4. This MOI serves as an early warning to the establishment, and no further actions are to be taken by FSIS at the time.

B. When an establishment is assigned to Category 3:

1. IPP assigned to the establishment, the FLS, and the DM, will receive an alert entitled, "Failure to Meet a Performance Standard," through the PHIS dashboard. During the next weekly meeting with establishment management, IPP are to explain that FSIS will be verifying that the establishment is taking corrective actions and reassessing their HACCP system (if necessary);

2. The FLS and the Inspector-in-Charge (IIC) are to correlate and evaluate the establishment's production history and corrective actions to determine when IPP should begin collecting follow-up samples. Although follow-up samples will be automatically assigned through PHIS, the samples are to be collected after corrective actions are implemented, and before the sampling collection window expires. Unless there are extenuating circumstances, IPP are to begin collecting follow-up samples approximately 30 days after receiving the Category 3 alert.

a. In most cases, FSIS will collect a set of 16 follow-up samples, with individual samples collected on a daily or per-shift basis whenever possible. Eight samples will be assigned if the Public Health Information System (PHIS) profile indicates the establishment does not produce the product subject to follow-up sampling more than three days a month;

b. FSIS will schedule a follow-up sampling set for the product when the establishment does not meet the performance standard only if one has not been scheduled within the previous 120 days. Establishments that remain in Category 3 longer than 120 days may receive follow-up sampling assignments upon request by OFO.

3. IPP are to notify establishment management that FSIS will assign follow-up sampling of the raw poultry product which exceeded a performance standard.

4. At establishments in Category 3, IPP are to use weekly meetings to discuss and document:

a. Observations from FSIS's verification tasks for establishment programs or procedures that specifically control *Salmonella,* including, but not limited to, procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operations as required by 9 CFR 381.65 (g), if applicable, as well as the HACCP plan, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite programs;

b. Results/data generated from the establishment's programs or procedures, including microbiological sampling data, verification of sanitary dressing operations or process control, and any regulatory waiver data, if applicable; and

c. The status of the establishment's actions to identify the cause of the failed performance standard, take corrective actions, and reassess the HACCP plan (if applicable) if the establishment has not done this already.

5. During the weekly meeting, IPP are to discuss and document their concerns when the establishment:

a. Proposes or implements corrective actions that are the same as or similar to actions taken previously when exceeding a performance standard, because continued failure to meet a performance standard brings into question the effectiveness of those actions;

b. Proposes or implements corrective actions for which the supporting rationale is not clear;

c. Produces validation data that does not appear to support the effectiveness of the intervention(s); or

d. Fails to review programs or procedures in a slaughter establishment that control *Salmonella*, including, but not limited to, procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operations as required by 9 CFR 381.65 (g), as well as the HACCP plan, Sanitation SOPs or other prerequisite programs); and

e. Fails to review its written procedures as required by 9 CFR 381.65 (g) during a reassessment, or when any significant changes were made to those procedures.

6. IPP are to document weekly meeting discussions in MOIs as described in FSIS Directive 8010.2. At a minimum, IPP are to document the status of the establishment's corrective actions and reassessment, if applicable.

V. VERIFYING REQUIREMENTS FOR AN ESTABLISHMENT THAT EXCEEDS A RAW POULTRY *SALMONELLA* PERFORMANCE STANDARD

A. IPP and EIAOs are to note that:

1. An establishment that does not meet a pathogen performance standard may not have adequately addressed *Salmonella* in its HACCP system;

2. If the establishment considered *Salmonella* reasonably likely to occur (RLTO) and addressed *Salmonella* in its HACCP plan, it must take corrective actions as required in 9 CFR 417.3 (a);

3. If the establishment considered *Salmonella* not reasonably likely to occur (NRLTO), it must take corrective actions and reassess its HACCP plan for that product to determine whether the HACCP plan needs to be modified to address *Salmonella* as required in 9 CFR 417.3 (b). To maintain an adequate HACCP system, the establishment may need to address *Salmonella* in its HACCP plan; and

4. Corrective actions taken in response to exceeding a performance standard must be documented in records subject to verification by FSIS as required in 9 CFR 417.3 (c).

B. IPP are to determine *if and how* the establishment responds to exceeding a performance standard.

1. IPP are to perform directed PHIS HACCP verification tasks to verify:

   a. If the establishment has reassessed its HACCP plan; and

   b. If the establishment modified its HACCP Plan, how it supports those changes.

2. IPP are to correlate with the EIAO and the DO through supervisory channels to help them determine whether the establishment's response to being assigned to Category 3 satisfies regulatory compliance.

3. If applicable, following the conclusion of the PHRE or FSA, IPP are to follow guidance from the DO to implement a verification plan.

VI. INSTRUCTIONS FOR COLLECTING FOLLOW-UP SAMPLES

A. IPP are to be aware that establishments will continue to be assigned routine samples (using project codes in the table below). IPP are to request supplies for follow-up sampling after receiving the tasks. Typically, 3-4 sets of supplies can be requested at the same time. Additional supplies will automatically be sent to IPP as submitted samples are received for analysis.

Table 2. Routine and follow-up sampling project codes, for poultry carcasses, chicken parts and NRTE comminuted poultry products.

Product	Routine Verification Project	Follow-up Sampling Project
Chicken Carcasses	HC_CH_CARC01	F_CH_CARC01
Turkey Carcasses	HC_TU_CARC01	F_TU_CARC01
Chicken Parts	HC_CPT_LBW01	F_CPT_LBW01
Comminuted Chicken	HC_CH_COM01	F_CH_COM01
Comminuted Turkey	HC_TU_COM01	F_TU_COM01

B. IPP are to use the same procedures and eligibility criteria for collecting routine and follow-up samples as outlined in FSIS Directive 10,250.1, *Sampling Instructions:* Salmonella *and* Campylobacter *Verification Program for Raw Poultry Products*.

C. Additional photo-illustrated examples of eligible product types under each poultry product group are available in IPP Help under "Raw Poultry Sampling Guidance."

D. Once follow-up sampling is initiated, IPP are to collect the complete set of follow-up samples as quickly as possible. If possible, one follow-up sample is to be scheduled for each subsequent production shift. However, when a routine sample has already been scheduled, the follow-up sample should be re-scheduled for another production shift. Samples submitted to the laboratory from two different shifts but marked with the same sample collection date will not be discarded, provided sample receipt temperature and packaging criteria are met as described in FSIS Directive 10,250.1.

VII. DISTRICT OFFICE ACTIONS

A. Every month, OPARM will send the DO a list of establishments in Category 3 to review and to use to schedule PHREs. As described in FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*, the DO is to schedule a PHRE within 30 days of receiving this list from OPARM. When feasible, EIAOs are not to initiate PHREs at Category 3 establishments until the follow-up sampling set has been collected and analyzed.

NOTE: If the establishment produces the product infrequently, it may not be possible to collect the entire follow-up sample set before the EIAO initiates a PHRE.

B. The DO may elect to schedule the PHRE (or FSA) before receiving the monthly OPARM list. In this case, the DO is to schedule a PHRE in the PHRE PHIS tool, select the reason as "establishment in PR/HACCP

Salmonella Category 3," and enter in the free text field "for cause PHRE due to establishment failed performance standard; poultry (identify product group).

C. The DO may elect to perform a PHRE for multiple product groups in Category 3 and is to verify that the establishment identifies and implements corrective actions for all affected product groups. In this case, for one of the product groups, the DO is to specify the other product groups covered in the free text field of the PHRE PHIS tool. For the other product groups, the DO is to enter into the free text field: "PHRE performed with PHRE for failed (name other failed performance standard) on MM/DD/YYYY."

D. The DO may elect to not schedule a PHRE when an establishment cycles in and out of Category 3 and had recently been assigned a PHRE or FSA for the same reason. Although cycling in and out of Category 3 is evidence of inconsistent process control, the short time since the previous PHRE or FSA may not allow for substantive changes at the establishment in response to the results. In this case, when the DO receives the OPARM list, the DO is to enter in the free text field, "PHRE performed for failed (name other failed performance standard) on MM/DD/YYYY."

VIII. EIAO ACTIONS DURING A PHRE OR FSA

A. Establishments typically incorporate multiple interventions or preventative measures to control *Salmonella* in raw poultry. Therefore, the establishment may not be able to identify a single intervention or preventive measure as responsible for not meeting a performance standard. Rather, the establishment's HACCP system, which incorporates all interventions and preventive measures, may not be effective to meet the performance standard. During the PHRE or FSA, the EIAO is to review documents supporting *Salmonella* control in raw poultry products throughout the process. For example:

1. If the establishment receives and further processes raw poultry (carcasses, parts, or comminuted product), does it understand the controls used by its suppliers to reduce *Salmonella* levels in raw poultry, does it receive letters of guarantee that suppliers meet purchase specifications or certificates of analysis, and/or does it verify the effectiveness of any supplier controls through audits or by sampling raw poultry at the receiving step?

2. If the establishment routinely measures *Salmonella* levels when receiving live birds or raw poultry products, does it understand whether the combined effects of the interventions documented in its HACCP system are sufficient to reduce *Salmonella* to a level that will consistently meet FSIS's performance standard?

3. If the establishment does not routinely measure *Salmonella* levels when receiving live birds or raw poultry products, does it provide a rationale to justify that the system will be capable of meeting FSIS's performance standards moving forward without this data?

B. The EIAO is to:

1. Conduct a PHRE using the methodology described in FSIS Directive 5100.4. The PHRE is to focus on the establishment's corrective actions and HACCP plan reassessment (if applicable), and the effectiveness of the establishment's system for controlling *Salmonella* in raw poultry products;

2. Review the establishment's historical data from the PHIS PHRE report, other background information described in FSIS Directive 5100.4, and MOIs generated from each weekly meeting. The EIAO is also to consult with the IIC or the FLS if there are questions about the status of the establishment's corrective actions and HACCP plan reassessment;

3. Determine whether the establishment is receiving a waiver of a regulatory requirement. If applicable, the waiver letter is available for review in the establishment PHIS profile. A current list of such establishments can be accessed at:

4. Verify that the establishment has been made aware of any *Salmonella* characterizing data provided in the quarterly establishment letter, including serotype, antimicrobial susceptibility, and Whole Genome Sequencing (WGS) results. The EIAO is to document the establishment's response to this information; and

5. Determine whether the establishment's WGS results match recent PulseNet cluster code(s). The EIAO is to make a request for this analysis through askFSIS using the title "PulseNet cluster analysis." The EIAO is to be aware that FSIS considers samples with WGS patterns assigned to a PulseNet cluster code to be of potential concern. The EIAO may be able to receive additional information about a matching cluster, including potential suspect product and where it may have been produced. This information, in combination with epidemiology and traceback, can be used to identify a product associated with a foodborne illness outbreak. The EIAO is to make establishment management aware of any WGS matches with recent clusters but is to take no further actions, unless instructed to do so through supervisorychannels.

C. The EIAO is to review the establishment's HACCP system documents and microbial sampling program results (i.e., for the pathogen(s) of interest or a suitable microbial indicator or a surrogate organism) if applicable, to assess whether the establishment was able to identify and respond appropriately to evidence that it is not controlling *Salmonella* in its raw poultry products.

Specifically, the EIAO is to:

1. Assess the establishment's response when its microbial sampling program results are consistent with FSIS's *Salmonella* results during the same time periods to determine:

    a. Why the establishment did not implement corrective actions in response to its own microbial sampling program results that indicate a failed performance standard and poor process control; or

    b. If the establishment did take corrective actions in response to its own microbial sampling program results, why the actions taken were unable to prevent the establishment from failing a performance standard.

2. Assess the establishment's response when its microbial sampling program results are inconsistent with FSIS's results, or if the establishment fails to provide support that it has implemented an effective program. As applicable, the EIAO is to verify whether the establishment:

    a. Initiated or revised a microbial sampling program with acceptable procedures for sample collection, sample preparation, laboratory analysis, and data (trend) analysis; or

    b. Specifically indicates its intention to implement additional corrective actions once its microbial sampling program is generating data.

NOTE: Developing or adjusting its microbial sampling program may be the only change in its HACCP system proffered initially by the establishment following system reassessment due to a failed performance standard because the establishment determines it must first be able to identify the problem through sampling and testing before it can accurately reassess its HACCP plan and determine where additional changes are needed.

D. In addition to evaluating microbial data, the EIAO is to determine whether there are trends in non-compliance, corrective actions, or other inspection findings of visible fecal contamination and septicemic/

toxemic carcasses, which may be evidence of poor process control.

E. If the establishment considered *Salmonella* to be RLTO when it exceeded a corresponding performance standard, the EIAO is to verify that the establishment identifies and eliminates the cause for exceeding the standard (9 CFR 417.3 (a) (1)), ensures that the critical control point (CCP) is under control (9 CFR 417.3 (a) (2)), takes measures to prevent recurrence (9 CFR 417.3 (a) (3)), and documents this response in records available for review by FSIS (9 CFR 417.3 (c)).

F. If the establishment considered *Salmonella* to be NRLTO when it exceeded a corresponding performance standard, the EIAO is to verify that the establishment takes corrective actions as required in 9 CFR 417.3 (b) (1-3), reassesses its HACCP plan as required in 9 CFR 417.3 (b) (4), and documents these actions as required in 9 CFR 417.3 (c). The EIAO is to determine whether the establishment's reassessment considers whether *Salmonella* can be controlled at all stages in their process.

G. If an establishment has performed a reassessment and continues to consider *Salmonella* as NRLTO (i.e., it addresses *Salmonella* outside of its HACCP plan, through its Sanitation SOP, or other prerequisite programs), the EIAO is to:

1. Verify that the establishment's reassessment documents include a rationale for continuing to consider *Salmonella* as NRLTO, and that this rationale is supportable;

2. Assess microbial sampling results from FSIS and the establishment before and after implementing corrective actions to understand the impact of any changes to the establishment's HACCP system on the rate of *Salmonella* positive samples, or a suitable microbial indicator or a surrogate organism;

3. Verify that the establishment has determined the cause for exceeding a performance standard, and has fully implemented corrective actions;

4. Verify that the establishment uses microbial sampling results from FSIS and the establishment's programs (including, but not limited to, FSIS's follow-up sampling set) to demonstrate it is better able to control the *Salmonella*; and

5. Verify that the establishment has considered its history of meeting FSIS's performance standards. For example, whether the establishment has been assigned to Category 3 for a significantly long time (for example, over one year), has repeatedly been re-assigned to Category 3, or produces multiple products which are assigned to Category 3.

H. The EIAO is to verify that all interventions cited in the HACCP system (including CCPs, Sanitation SOPs, or other prerequisite programs) are validated to effectively control *Salmonella* in raw poultry as required by 9 CFR 417.4 (a) (1). Each intervention must be demonstrated as capable of reducing *Salmonella* when used under the validated conditions by the level described in the scientific or technical support. To verify that this requirement is met, the EIAO is to refer to FSIS Directive 5100.1, *Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology*.

I. At the conclusion of the PHRE, the EIAO is to document why an FSA is or is not recommended, to be considered by the District Manager or designee, after considering:

1. Whether the establishment identified the cause for exceeding a performance standard, and if applicable, how this identified cause guided the establishment's design of corrective actions, and HACCP plan reassessment. The EIAO is to explain how the establishment supported its decision-making process;

2. The current implementation status for the establishment's corrective actions and HACCP plan reassessment, if applicable;

3. Whether the establishment documented *Salmonella* as a biological hazard RLTO in its HACCP plan. If the establishment considers *Salmonella* as NRLTO after exceeding a performance standard, explain how the establishment supported this decision;

4. Whether the establishment's corrective actions were effective, based on an assessment of FSIS sampling results and inspection findings (e.g., visible fecal contamination and other inspection observations), and the establishment's microbial sampling programs before and after implementation;

5. Whether the EIAO was able to adequately assess any establishment-generated data in support of Parts C above and the results of this assessment, if applicable;

6. Whether the establishment has been assigned to Category 3 for a significantly long time (for example, over one year), has repeatedly been re-assigned to Category 3, or produces multiple products which are assigned to Category 3; and

7. Whether the establishment is participating in SIP as a condition of receiving a waiver of a regulatory requirement. If so, the EIAO is to determine whether the establishment fully complied with SIP program requirements as documented in the approval letter. If not, see Section X.E.

J. If an FSA is scheduled, the EIAO is to conduct it using the methodology described in FSIS Directive 5100.1. The FSA is to focus on the establishment's corrective actions and HACCP plan reassessment (if applicable) performed in response to exceeding a performance standard, and the establishment's system for controlling *Salmonella* in raw poultry products.

K. For establishments that do not meet a performance standard while operating under one or more waivers of FSIS regulations, the EIAO is to assess whether the establishment's HACCP plan reassessment (if applicable) specifically addresses the impact of any waivers on failing a performance standard. The reassessment should assess any applicable data and/or other supporting documentation to determine if the procedures under which the establishment is operating as a result of the waived regulation are sufficiently preventing contamination and not contributing to the failed performance standard.

IX. ENFORCEMENT

A. DOs are not to issue a Notice of Intended Enforcement (NOIE) or suspend inspection based solely on the fact that an establishment exceeded a performance standard. However, exceeding a performance standard can indicate that applicable criteria in 9 CFR 500.2 through 500.6 are met (e.g., if a HACCP system is found to be inadequate, Sanitation SOPs have not been properly implemented or maintained, or sanitary conditions have not been maintained). District Offices are to take an enforcement action when an establishment exceeds a performance standard and applicable criteria in 9 CFR 500 are met.

B. Per 81 FR 7285, if an establishment fails to implement corrective actions after 90 days of being notified that it is in Category 3, and the establishment continues to be assigned to Category 3, the District Office is to determine whether additional enforcement action is needed, including issuance of a NOIE, Notice of Suspension (NOS), or Notice of Reinstatement of Suspension (NROS) as described in 9 CFR 500.

C. When making and documenting enforcement actions under 9 CFR 500, the District Office is to refer to:

1. 21 U.S.C. 453 (g) (3) after assessing compliance with parts of 9 CFR determined to be relevant to controlling *Salmonella* in raw poultry products, including, but not limited to, 9 CFR Parts 416 and 417, and 9 CFR 381.65 (f) and (g);

2. 21 U.S.C. 456 after verifying non-compliance with 9 CFR part 416, if the establishment is failing to

prevent processing cross contamination or identifies equipment-related zero tolerance failures; or

3. 21 U.S.C. 453(g) (4), if the establishment's products were associated with human illness.

D. If the EIAO determines that an establishment's procedures allowed under a waiver are contributing to the failed performance standard, and that the establishment has not satisfactorily addressed this determination, the District Office is to refer to FSIS Directive 5020.1, V*erification Activities for the Use of New Technology in Meat And Poultry Establishments and Egg Products Plants*, to determine if the waiver should be rescinded.

E. FSIS does not consider raw poultry containing *Salmonella* to be adulterated as defined by 21 U.S.C. 453 (g) (1) unless other circumstances make the product adulterated. Establishments are not required to segregate or hold product when the establishment exceeds a performance standard. However, if the District Office determines that the product is injurious or otherwise adulterated as defined by 21 U.S.C. 453 (g) (3) or (4) or 456, IPP and the EIAO are to verify that the establishment segregates and holds affected product.

X. QUESTIONS

Refer questions regarding this notice to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development