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Introduction to Risk-Based Food Inspection II - The Process of Inspection

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**Workshop on Improved Food Inspection
Capacity Building Based on Risk Analysis
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Introduction to Risk-based Food Inspection II

The process of Inspection

APEC PTIN Workshop on Improved Food Inspection Capacity Building Based on Risk Analysis (May 21-23, 2014; Seoul, Korea)

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Overview/ Outline of the presentation

- **Objective and scope**
- **Development of risk-based inspection plan**
- **Preparation for inspection**
- **The inspection process (with opening meeting, inspection and closing meeting),**
- **Document review including product list and flow diagram**
- **Facility assessment - Facility, Product, Equipment, Employees, Raw material, etc.**
- **Documentation, reports and records**
- **Post inspections activities**
- **Checklists and their uses**
- **Some examples**

Objective and Scope

- **Objective**

- To assess adequacy, effectiveness of facilities controls for addressing all FB disease risk factors identified for products
- To examine possibilities for improving systems that are in place and for progression to a HACCP based process
- To improve quality and safety management system continuously

- **Scope**

- The inspection of food processing facilities covers the entire process, ie the set of procedures for active managerial control of FB disease risk factors established by food processor to help ensure safety of food products

Risk-based Inspection Plan



Prepare for Inspection



Inspection Process



Post-inspection Activities

Risk-based inspection Flow chart

Risk-based inspection Plan

- Categorize food businesses based on risks
 - Sector specific risk factors
 - Company specific risk factors
- Develop annual inspection plans
 - Account for planned inspections (quarterly also)
 - Account for non-planned inspections (new businesses, complaints)
- Identify if inspected by more than one authority – team of inspectors

Risk-based inspection Plan

Calculate total number of inspections

- Total businesses – 1000
 - 4 inspections/ year – 50 businesses = 200 (HR)
 - 3 inspections/ year – 200 businesses = 600 (MR)
 - 2 inspections/ year – 300 businesses = 600 (LR)
 - 1 inspection/ year – 400 businesses = 400 (VLR)
- Total planned inspections/ year = 1800**

Inspection	Year 2014			
	Q1	Q2	Q3	Q4
Planned	450	450	450	450
Non-planned	10	10	10	10
Food safety investigation	25	25	25	25

Preparation for inspection

Preparation for Inspection

- Scheduling the inspection
- Review of previous records – registration information, information about business
- Providing information to/ notifying food business
- Prepare inspection material

Scheduling the inspection

- **Identification of food businesses - Check inspection plan, identify businesses to be inspected during this trip**
 - Priority to high-risk businesses; those overdue/ require follow up inspection
 - Grouping inspection of particular types of businesses (e.g., slaughter, manufacturing, market vendors) to minimise cross contamination.
- **Determine size & members of inspection team – any specialists**
 - Identify participants; confirm availability; rescheduled if unavailable
 - Ensure adequate time provided for assessing food business
- **Schedule in adequate time for sampling, incl transport to lab**
- **Check if any education material to be distributed -new rule/GHP**
- **Review annual sampling plans for product, ingredient, environmental samples**
 - Verify if samples to be taken (chemical, microbiological, others)
- **Contact laboratory to verify sample requirements, sample transport conditions and to coordinate for sample submission.**

Review of previous records

- **Registration information – premise licence, health certificate**
- **Information about business**
 - general information (owner, key personnel, location, operating schedules)
 - Specific information – size and complexity of business, products
- **Inspection records from previous inspections**
 - Earlier report
 - Corrective actions on non-compliances
 - Results of testing of samples
- **Other pertinent documentation - Any other FSMS certifications, SOPs, reports of other audits, etc**
- **Any customer complaints**
- **Additionally**
 - Operations many and complex, more than one product handled - Risk factors and critical steps not so easy to identify
 - Review common operations and risk factors ahead of inspection
 - Perform risk-based inspection of risk factors

Notifying food business of Inspection

- Announced inspections
 - Inspections of larger businesses
 - Notification can increase effective use of resources
 - Minimise delays, ensure management available, processing functioning, documents available
- Unannounced inspections - follow up inspections or complaint inspections
- Notifications through letter, e-mail, phone – recorded in file, confirm

Prepare inspection material

- Basic material for all inspections
 - Notebook, pen, checklist, torch, thermometer, disinfectant
 - Appropriate clothing (e.g., lab coat for processing inspection)
 - Specialised equipment e.g pH meter, lactometer
- Any reference documents (legal references, food standards)
- Appropriate sampling/ sealing material
 - Cooler/icebox, ice packs, sterilized containers for water & ice collection, permanent marking pen for sample identification, sterile gloves, sterile swabs and sample bags/containers
 - Sampling protocols (e.g., finished product, ice/water, swabs)
 - Forms for sample submission to the laboratory
- Photographic equipment
- Collect the appropriate IEC materials to be distributed
- All equipment/ materials clean and in working order

The inspection process

- Opening meeting
- Familiarization tour
- Inspection
 - Document review including product list and flow diagram
 - Site inspection
 - Completion of check-list/ report/ non-conformity report
- Closing meeting
- Documentation and reporting
- Post inspection activities including follow up of corrective actions

Inspection techniques

- Observation
- Inspection e.g. checking cleanliness
- Measuring e.g. temperature, pH, weight, time
- Sampling and analysis
- Questioning
- Record review – health, training



Opening Meeting 1/2

- Schedule opening meeting
- Open meeting with introductions, show official identification
- Sign establishment register, as needed
- State inspection objectives, scope, outline/schedule –sequence of actions (eg document review; walk through inspection, site evaluation, closing meeting). Not applicable for small businesses
- Assure management of confidentiality
- Ensure management collaboration for improving food safety/Q
- Arrange for representative presence during inspection;



Opening Meeting 2/2

- Ask about any specific establishment requirements – hygiene/ operations
- Arrange for place - review documents/discuss follow up
- Check for any changes since last inspection
- Inform inspection techniques - notes, observations, questions, etc
- Confirm that final meeting after completing inspection to discuss observations/ findings
- Indicate if you will provide report at that time
- Notes of discussion important

Inspection - document review

- Product lists and Process flow diagrams
- SOPs and records
- Specifications
- Procedures/ operational processes
- Sanitation protocols
- Pest control protocols
- Personnel requirements
- Records

Product lists and flow diagrams

- Obtain a product list
- Obtain or prepare a process flow chart – graphic depiction of all major operations
- Use the flow chart to anticipate critical steps in ensuring product safety

CCP, CL, process validation and CCP control records

Critical Control Points (CCPs)

- Determine operations critical to product safety
- If HACCP system in place, ensure that CCPs are integral part of HACCP plan
- If not determine whether plant personnel are aware of risk factors inherent to each product and operation
- Determine that control measures for each risk factor are in place

Critical Control Point

- CCPs are those points/ steps where a control measure can be implemented to prevent, eliminate or reduce to acceptable levels any of the hazards identified for a product

CCP, CL, process validation, CCP control records

Critical Limits

- Ascertain that CLs used are appropriate
- Determine that CLs being observed
- Determine that corrective actions are in place in case the CLs limits are not reached

Process validation

- Verify that controls in CCPs are effective meet the requirements of the quality and safety management system
- Records substantiated by analytical results

CCP control records

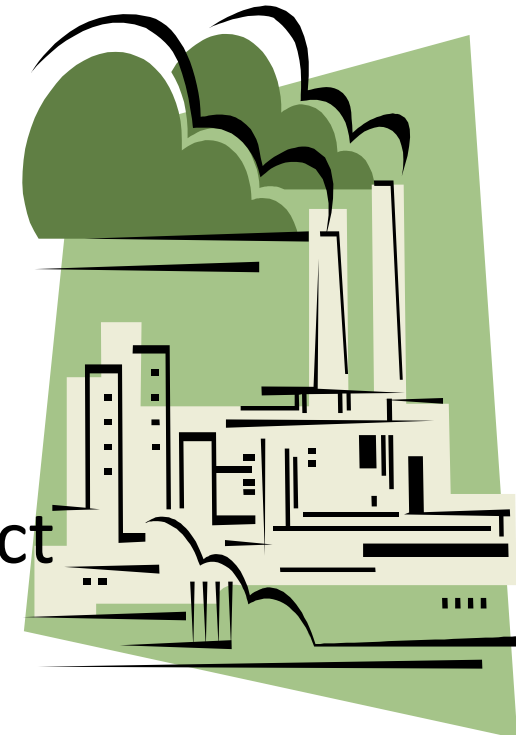
- Review CCP control records

Familiarization tour/ walk through

- Gain orientation
- Size and layout
- Types of products being manufactured
- Not-needed on follow-up inspections – except if major modifications
- Clean to dirty area

Inspection – site inspection (external)

- **External environment, building design and construction**
 - Location - pollution, flooding, infestation
 - Building design and construction – good repair state, prevent entry of animals and pests, debris, fumes
- **Zoning and separation** – smooth product flow, ease of cleaning, raw material and finished product handling separate
- **Plant services** – Power back up, water and its analysis, waste removal facilities



Inspection – site inspection (internal)

- Layout and process flow
- Internal structures and fittings
- Cleaning facilities and procedures
- Pest control procedures
- Personal hygiene practices and practices
- Facility environment and storage
- Water and ice
- Equipment
- Drainage, waste/ inedible substances
- Raw material and ingredients
- Product
- Packaging and labelling

Inspection - site inspection (internal)

- Layout and process flow
- Facility assessment
- Product assessment including food additives, non-food chemicals, packaging material
- Manufacturing equipment
- Employees and staff
- Raw material
- Sanitation
- Pest control

Layout and Process flow

- Premises, sites and/or plants should be **designed, constructed and maintained** to control the risk of product contamination.
- Layout should be clear; **product flow**, as far as possible, should be uni-directional – no crisscrossing
- Adequate **separation** between storage areas (raw material, packaging material, finished goods, rejected/ accepted materials, etc.), processing area, packing area, utility area etc.

Facility Assessment

Internal structures and fittings

- Walls, floors, ceilings and other structures designed to prevent entry of pests, water, made of durable materials and easy to maintain, clean and disinfect
- Surfaces of walls, partitions and floors made of impervious materials; have a smooth surface, wall/floor joints conclave
- **Floors** constructed to allow adequate drainage & cleaning;
- **Ceilings** and overhead fixtures accessible for cleaning, to minimise possibility of dirt or condensation, falling in processing area/ on food or food contact surfaces
- **Windows** easy to clean, designed to prevent entry of pests
- **Doors** have smooth & non-absorbent surfaces, easy to clean/ disinfect, designed to prevent entry of pests, self-closing
- **Food contact surfaces** are in good condition, durable and easy to clean, maintain and disinfect.

Lighting, temperature, ventilation

- **Lighting** – natural/ artificial adequate for operations (colour, intensity); fixtures protected / shatter proof; check at night; inspection areas,
- **Temperature**
 - operations and environment appropriate
 - Equipment monitored and controlled appropriately for characteristic that need monitoring - temperature, airflow, humidity (e.g., HACCP critical limits).
 - Verify temperature in room/ equipment and temp log sheets
- **Power backup** - e.g. generators, invertors for uninterrupted supply, as necessary
- **Ventilation** system
 - remove air borne contamination, control odours and humidity
 - Air not circulated from unclean to clean areas
 - ventilation equipment maintained (good repair state) and clean

Water, ice and steam

Water

- Water for processing, cleaning equipment/ floors to be potable
- Verify adequate supply of potable water or a source approved by the municipality / appropriate authority
- If water stored in containers, verify protection from contamination (covered) & utensils do not contaminate water
- Water not be re-used (as risk of contamination increases)
- Review the laboratory report or take sample for verification

Ice

- Ice that comes in contact with food to be from potable water and be produced, handled and stored to protect from contamination
- Ice for raw material & final product not come in contact

Steam and other uses

- Steam production, capacity & pressure to be adequate for processing & cleaning.

Drainage, waste/ inedible substances

- **Drainage design and construction** – impervious rust proofing material, covers and traps to avoid entry of pests, for effective cleaning, not allow stagnation/ backflow of water. No overhanging of sewage or sanitation pipes.
- **Sewage disposal** – comply with country regulations
- **Waste containers and bins and disposals**
 - Containers for waste, by-products and inedible or dangerous substances to be suitably constructed
 - Waste bins and areas identified, covered and kept clean.
 - Waste removed frequently - not accumulate in processing/ storage areas.
- **Check drainage map and plan and waste disposal site and plan**

Storage facilities

- **Storage facilities** – adequate for food, ingredients that are installed to facilitate maintenance, cleaning
 - Are there separate storage facilities for raw product and finished food in order to prevent contamination
 - Are the storage facilities in good repair and able to prevent access by pests and maintain appropriate temperature and humidity and temperature control to minimize deterioration

Product Assessment

Product

Product storage

- examine product dry storage area for evidence of moisture/ pests.
- If freezing/ refrigeration required, examine temperature - thermometers/ loggers
- Check if FIFO system followed

Product loading and transportation

- Examine how product is protected from damage due to exposure to sunlight, rain, dust, insects etc
- Products requiring cold storage not left in ambient temperatures
- Examine condition of transportation vehicles
- Vehicle should not used for transport of hazardous material, live animals & waste material.

Product

Product labeling and identification

- Check product labeling according to legal requirement
- Label to have description of product, manufacturer, list of ingredients, net wt. expiry/BB date; any handling, storage and use information
- Check distribution records – for recall

Package closure and code

- Examine package closures for integrity and product protection.
- Check code on package indicating batch or lot number and manufacturing date

Product sampling and testing

- Samples may be taken before or during inspection for testing

Product

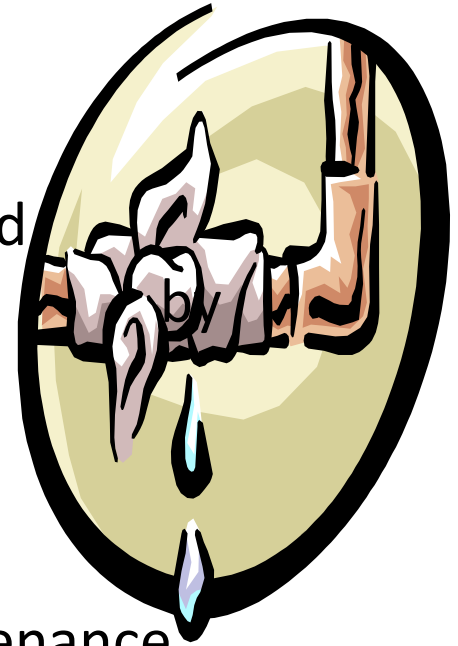
Other material

- **Food additives** - Check that the food additives and levels being used in products are approved.
- **Non food chemicals** - Check that non food chemicals are received, handled and stored separately.
- **Packaging material**
 - Ensure packaging material approved for food use
 - Check for compliance with specifications
 - Check that packaging material adequately stored (protected)
 - Verify that reusable packaging is appropriate to the product, easy to clean and disinfect

Manufacturing equipment Assessment

Equipment

- **Design & material** – non-toxic, not contaminate food, non-corrosive, design such that not contaminated lubricants, dripping condensation, etc
- **Location** – functions in accordance with intended use, can be cleaned and maintained
- **Maintenance and calibration** – good state of maintenance, measuring devices to be calibrated – check maintenance and calibration programmes
- **Product residue, condensation, splashing** - No accumulation of product residue on equipment, dripping of condensation on food (pipes, etc), no splashing of wash water/ liquids
- **Filter and lubrication** - examine filter cleaning schedule, lubricants to be approved for such use, examine the potential dripping of lubricants on products.
- **Cleanliness and sanitation**





Employee facilities Assessment



NO SMOKING

**IT IS AGAINST THE
LAW TO SMOKE IN
THESE PREMISES**

Personal hygiene facilities & practices

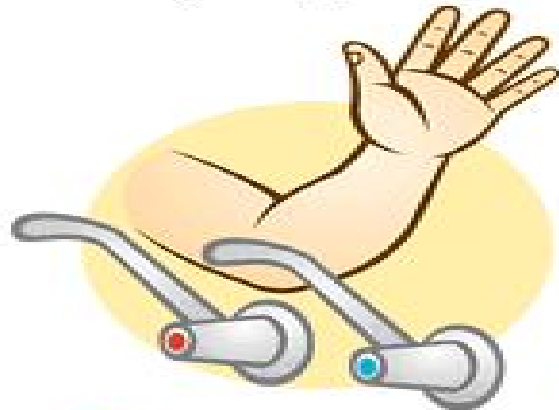
- **Health status** – health checks and records, employees suffering from diseases not allowed to handle exposed food
- **Employee facilities** - adequate hand washing, toilets facilities & cleanliness; changing and eating facilities, storing personal belongings, as adequate; location of facilities – eg hand washing stations; availability of hand drying facilities
- **Personal hygiene and sanitation practices** – use of clean protective clothing, hand washing, use of soap and disposable towels
- **Personnel behaviour** –Smoking, eating, chewing, sneezing, drinking and spitting, wearing personal effects
- **Employee training** – check sanitation program and records of employees; Examine awareness on GHP

How to wash your hands

How to wash your hands



6 Dry with paper towel



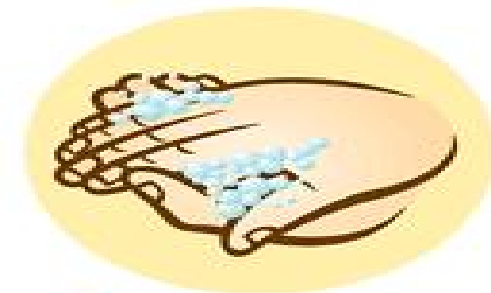
5 Turn off water lever using your elbows



1 Wet your hands



2 Apply solution and scrub for at least 15 seconds



3 Scrub back of hands, wrists, between fingers and under fingernails



4 Rinse your hands

Raw material Assessment

Raw material and ingredients

Raw material reception

- ❖ Examine cleanliness of transport vehicles, temperature of perishable raw material.
- ❖ Record keeping at the reception stage to be observed.

Raw material handling and sorting

- ❖ Material not placed directly on the ground
- ❖ Perishable material not remain long on unloading dock.
- ❖ Hazardous substance not received in the same location.

Raw material storage

- ❖ Stored properly, perishable goods refrigerated or placed in frozen storage.
- ❖ Hazardous substance stored separately from the material

Stock rotation

- ❖ observe the in and out movement of raw material
- ❖ Check if FIFO rule followed

Specification and lot identification

- ❖ review the records for product traceability.

Sanitation and pest control Assessment

Sanitation facilities and protocols

- **Cleaning procedures** - Check the protocols and actual process for consistency; meet the person(s) responsible for cleaning procedures and verify by asking questions about the process
- **Verify facilities** – Verify adequacy for storing cleaning equipment and supplies, supply of potable water
- **Cleaning and sanitizing chemicals** - should be approved and clearly identified; m/f instructions followed

Pest control programmes



- Examine the pest control protocol and schedule (documented)
- Examine that pest control operator is trained & licensed.
- Check the building's pest access/ barriers on window, doors and wall tops, holes/ drains - examination for any signs of pests
- Check storage of pest control products
- Is process consistent with procedures described
- Are products being used approved/ as per law
- Check bait/ trap map
- Check for any food safety hazard
- Check application records



Completion of check list/ report/ NC report

- Review notes taken during inspection
- Complete checklists/ report in format
- Assign ratings/ comments
- Complete report (format) including non-conformity reporting and corrective action plan



Closing meeting

- Ensure presence of management personnel – especially senior level
- Highlight key observations - discuss findings, positive, non compliances/ violations
- Explain implications of non-compliances
- Establish a timeline for correction of non-conformities
- Discuss possible improvements to quality/ safety management system
- Provide written report with corrective action plan (signed)

NON CONFORMANCE REPORT

A Non Conformance Report is issued by a Inspection Authority to a food business which is found during routine inspection activity to be operating in contravention of current Laws and Rules.

Report No. _____

Date _____

Inspector		Page No. of
Name of Food Premises	License No.	Manager/Person in Charge
Address		

NON-CONFORMANCE DETAILS:

CORRECTIVE ACTION DETAILS:

Corrective action will be completed by: *(insert date)*:
/...../201.....

I understand/agree with the non-conformance (s) and will implement the corrective action described above.

Signature *(Manager/Person in Charge)* Date:/...../201....

Signed *(Inspector)*: Date:/...../201....

FOLLOW-UP INSPECTION: Inspector to check Corrective Action has been completed

Signed *(Inspector)*: Date:/...../201....

Documentation, reports & records 1/2

- Documentation of inspection consists of two parts:
 - The company report in a specified format - provided to establishment at the closing meeting
 - The establishment report -full documentation of inspection & filed & includes:
 - ✓ *Inspector notes,*
 - ✓ Checklists used and any lists of non-compliance, with associated rating.
 - ✓ Copy of the report provided to the food business,
 - ✓ Examples of labels, photos or other evidence
 - ✓ Samples taken and results

Documentation, reports & records 2/2

- **Reports should:**
 - Be clearly written, concise, accurate, contain all pertinent information and be accessible
 - Be focused on objective evidence, observations with the use of clear and concise statements.
 - State the facts and avoid stating inspector opinions.
 - Include all the information pertinent to the inspection, including sample collection and corrective actions.
 - Clearly define the limitation of inspection, if you did not inspect certain building or view certain documents, identify those in your record.
 - Give both indicators of compliance and any infractions observed
 - Summarize the NC issues and give the references of standard and area where non compliance issue observed

Report example

Food Business Inspection Report		Report #	
Food Business Name		Registration number	
Food Business Owner			
Address		Telephone (Business) Telephone (Manager/Owner)	
Manager/Operator (if different from owner) Name, Title		Inspection Date	
		Inspection type Scheduled, Follow up, Food Investigation	
		Food Products	
Facility type (e.g., dairy, bakery, market vendor, food service, retail)		Food Products	
Name of the Inspector		Date & signature	
Food Business Inspection Report (Non compliance)		Report #	
#	Inspection element	Rating	Observation
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Post inspection activities

- File report
- Schedule follow-up inspection if needed - to verify corrective actions – normally unannounced
- Test results/ report (if samples drawn)
- Review if level of inspection needs to be reduced

Flow chart

Risk-based Inspection Plan



Prepare for Inspection



Inspection Process



Post-inspection Activities

- ❖ Scheduling the inspection
- ❖ Review of previous records of business
- ❖ Providing information to food business
- ❖ Prepare inspection material
- ❖ Review risk factors and perform risk-based inspections of these

- ❖ Opening meeting
- ❖ Familiarization tour
- ❖ Inspection
 - Document review (product list /flow diagram
 - Site inspection
 - Complete check-list/ report/ NC report
- ❖ Closing meeting
- ❖ Documentation and reporting

- ❖ File report
- ❖ Schedule follow-up inspection to verify CA
- ❖ Test results/ report (if samples drawn)
- ❖ Review level of inspection

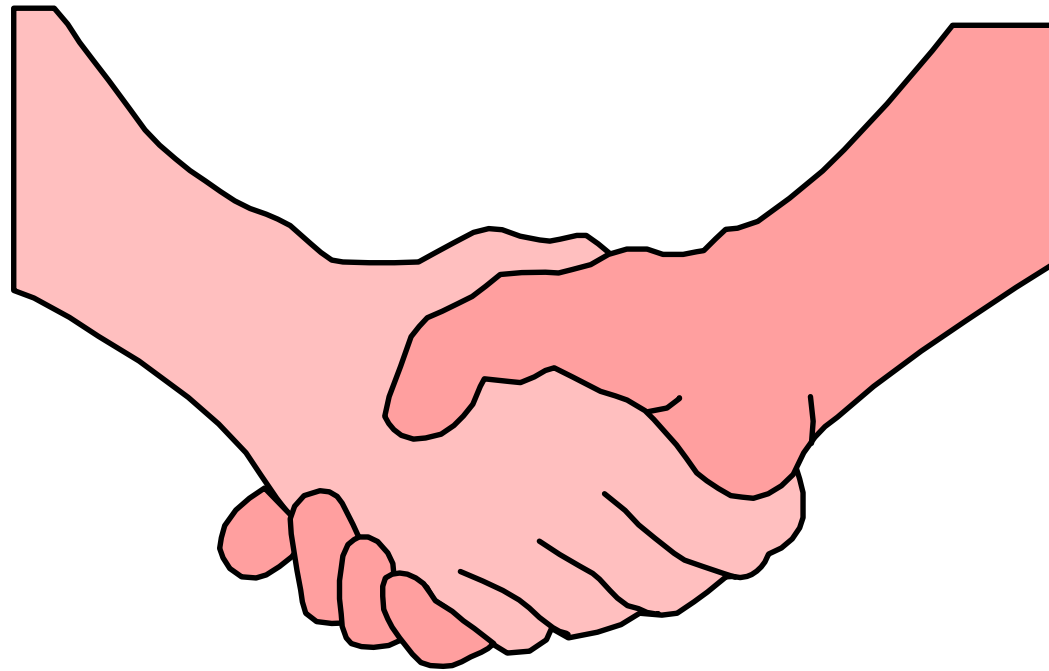
Checklists - use and examples

- provide structure and continuity to an audit;
- ensure a consistent audit approach;
- ensure that the audit scope is being followed;
- help to ensure that audit conducted systematically and comprehensively;
- act as a time manager;
- ensure that adequate evidence is obtained;
- provide a means of communication and a place to record data for use for future reference;
- provide a record of audit and objective evidence that audit performed;
- used as an information base to plan future audits;
- serve as a memory aid



[Checklist format](#)

THANK YOU



Packing material stores



Stored Packaging Materials



Floor corners



Flaking on ceiling



Unhygienic Washing of Raw Material



Packaged Material



A view of Stored Material



TRANSPORT DAMAGES



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TRANSPORT DAMAGES



Surroundings of processing Plant



Products kept in sun/ outside



Cleaning in Running Water





Hand Washing Facilities



Shoveling of Flaked Ice



Chill Room



Cold Storage

