Identity Preservation

Applying and Managing Identity Preservation Concepts to Maintain Provenance

Development

To define detail, scope and purpose.

Development

This information can be used to develop food safety and quality programs that meet the requirements of modern Regulatory, Customer and Industry Standards:

- We take the time to explain the expectations and requirements of food safety and quality compliance as these relate to your food safety and quality programs.
- You may choose to use our Premium Resources to build, enhance or upgrade your food safety and quality program.
- We encourage you to share this webpage with any food compliance associates and peers you believe may benefit from our commitment to providing our users with user friendly information and resources to achieve superior Food Compliance Culture.
- We welcome your suggestions for additions of general or specific content through the haccp.com Contact Page.

Key Definitions for Identity Preservation

- Categorised Identity-Preserved Status: The status of food items or ingredients that belong to a general category, such as organic, free range or non-GMO, rather than to a specific name.
- Certificate of Analysis, C of A, or COA: A document that reports and certifies the test results of a product, commonly including confirmation of chemical, microbiological or physical composition.
- Genetic Profiling: Laboratory analysis of DNA to identify a species, variety or genetic status by comparison against established markers.
- Genetically Modified Organism or GMO: A plant, animal or microorganism whose genes have been altered through genetic modification, by the inclusion of foreign genetic material or by the alteration of some DNA. The foreign material may come from individuals of the same or a different species, or it may be synthetic.
- Identity Preservation: Identity preservation is the practice of tracking the details of raw materials, work in progress and finished foodstuffs so that the specific characteristics of each product lot are known.
- Mass Spectrometer: A scientific instrument that ionises sample molecules and separates the ions according to their mass-to-charge ratio to identify chemical composition.
- Named Identity-Preserved Status: The status of food items or ingredients that are defined by a specific name, such as a breed, a geographical origin or a registered trademark, rather than by a general category.
- Product Identification and Traceability: The method used to ensure that all items, including raw materials, packaging, work in progress and finished products, are identifiable and traceable to their source. See Product Identification and Traceability.
- Titration: A process in which a carefully measured amount of a well-characterised chemical substance is added to a substance of unknown concentration until a complete reaction has occurred. Titrations are used in chemical analysis to determine the concentration of substances within a solution.

Identity Preservation Development

When considering the development, documentation, and implementation of Identity Preservation within food safety and quality management systems, the following information should be considered to ensure effective outcomes:

About Identity Preservation

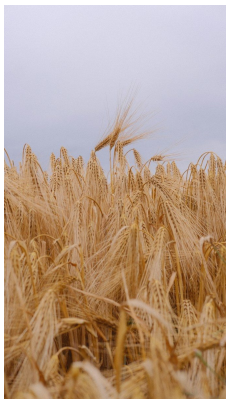
Identity preservation procedures are important to ensure the identification and traceability of specified items are maintained. Identity preservation is relevant to products including those with claims regarding composition, sourcing, or status as a named or categorised product. Consumers rely on the identity preservation process to be maintained to ensure ongoing confidence in the foods they purchase.

Named Identity-Preserved Status

Named identity-preserved status includes food items or ingredients that are defined by a specific name, rather than by a general category. Examples of named identity-preserved items may include:

- Food or ingredients identifiable as a designated species or registered varieties of plant or animal, for example, a specific breed of sheep;
- Food or ingredients identifiable as sourced from specified geographical regions, for example, Parma ham;
- Food or ingredients identifiable as produced or manufactured to specified standards, for example, foods manufactured under a registered trademark or through a specific technology.

Categorised Identity-Preserved Status



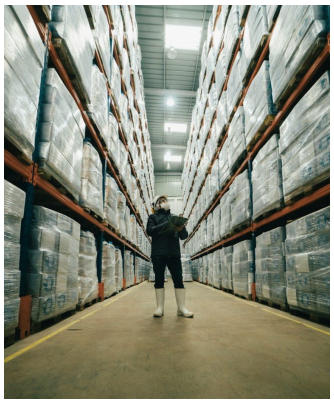
Claims such as non-GMO or organic describe a category of product rather than a single named item.

Categorised identity-preserved status includes food items or ingredients that are from a general category, rather than a specific name. Examples of categorised identity-preserved items may include:

- Food or ingredients identifiable by their genetic status, for example, GMO;
- Food or ingredients identifiable by their purity or chemical-free status, for example, Organic;
- Food or ingredients identifiable by their method of production, for example, Free Range.

Food items can be categorised as a combination of named and categorised identity-preserved status.

Maintaining Identity Preservation



Organised, separated storage helps keep identity-preserved items apart and traceable.

Identity preservation depends on controls that keep identity-preserved items separate and identifiable at every step, from receival to dispatch. Controls commonly include:

- Specifications that state the identity or claim requirements for each item, such as origin, variety or genetic status. See Specifications Management;
- Supplier assurance through the approved supplier program, including current certificates, declarations and Certificates of Analysis;
- Segregation at receival, storage and production, by physical separation, time or dedicated equipment. See Storage and Handling Requirements;
- Clear labelling of identity-preserved items and finished products. See Labelling Standards;
- Cleaning and changeover procedures that prevent carry-over between identity-preserved and other items;
- Lot level identification and traceability through every stage, supported by mass balance reconciliation. See Product Identification and Traceability;
- Consideration of claim integrity within the food fraud risk assessment, because identity claims can be targets for substitution.

Verifying Identity-Preserved Status



Analytical instruments such as a mass spectrometer can verify the chemical profile behind an identity claim.

As with all food products, it is important to be able to confirm claims made regarding composition or identity status. In this context, careful consideration must be given to ensuring the verification methods employed to prove any claims being made are correct. Verification requirements for identity-preserved foods or ingredients are often much more complex than those applied for general Product Assessment and Testing. Examples of verification activities for identity preservation include:

- Species of plants or animals can be verified through genetic profiling against established markers;
- Food or ingredients sourced from specified geographical regions can be verified through genetic profiling. This is generally an option where there is a controlled genetic pool, and no extensive cross-breeding is facilitated. Chemical profiling using devices such as a mass spectrometer can also be used to map unique chemical content factors relevant to a specific geographical region;

- Microbiological, chemical, and physical assessments and testing can be applied to verify the status of foods or food ingredients manufactured under a registered trademark or through a specific technology;
- Genetic status, such as non-GMO status, can be verified through genetic profiling against established markers;
- Purity or chemical-free status can be verified through the application of a mass spectrometer, or simple chemical analysis techniques such as titration;
- Methods of production can be verified through microbiological, chemical, and physical assessments and testing.

A certification or accreditation is not a guarantee of conformance regarding identity preservation. It confirms only that the systems used to manage identity preservation are in place. Outcomes of product Assessments and Testing provide confidence that the identity preservation claims being made are accurate. It is common for food businesses using identity-preserved foods or ingredients to request a Certificate of Analysis upon receipt of their 'Identity-preserved' items to demonstrate conformance. If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific identity preservation requirements in relation to their items.

References

- ISO 22000:2018 Food safety management systems
- Codex Alimentarius codes of practice

Identity Preservation Development Key Points

- Identity Preservation programs must be developed to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The Senior Management of your business facilitate a commitment to ensuring adequate resources to the development of your Identity Preservation program;
- Should you require additional resources for the development of Identity Preservation program elements, please discuss this with the relevant Senior Management representative;
- A properly developed Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly-developed Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Documentation

To establish the developed detail in a viewable format to facilitate information.

Documentation

Document: A document provides guidance and/or direction for performing work, making decisions, or rendering judgments that affect the safety or quality of the products or services that customers receive.

Documented policies, procedures, work instructions, and schedules form the basis of any food safety and quality management system. The following documentation formats may be considered to ensure ongoing compliance with specified requirements for Identity Preservation:

- Identity Preservation policy;
- Identity Preservation development procedures;
- Identity Preservation implementation procedures and work instructions;
- Identity Preservation monitoring procedures;
- Identity Preservation corrective and preventative action procedures;
- Identity Preservation verification schedule;
- Identity Preservation verification procedures;
- Identity Preservation validation schedule;
- Identity Preservation validation procedures;

- Identity Preservation training procedures.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Documentation requirements in relation to their items.

You may wish to visit the Identity Preservation Templates section of haccp.com for examples of Identity Preservation documentation, record, and resource formats commonly applied within food safety and quality systems.

Identity Preservation Documentation Key Points

- Identity Preservation programs must be documented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- All documented Identity Preservation program elements must be controlled to ensure compliance;
- Key documented Identity Preservation program elements should be available to your business team at all times to ensure they can facilitate required tasks;
- A properly documented Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly documented Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Implementation

To facilitate the application of the documentation.

Implementation

Implementation: Implementation is the application of documented food safety and quality system elements into the actual business operation.

The implementation of Identity Preservation within any food business requires genuine commitment from senior management, staff, and visitors to ensure the nominated goals of implementation are achievable on an ongoing basis. It is a step that requires significant planning and consideration of general and specific food business circumstances to ensure the outcomes of Identity Preservation do not negatively impact the safety and quality of the food items dispatched from the business.

Implementation of Identity Preservation must include a clear definition of responsibilities and authorities for all levels of participation by senior management, staff, and visitors to the site.

When implementing Identity Preservation within food safety and quality system, you may wish to consider the following requirements before completion:

- Communication and display of the Identity Preservation policy;
- Completion of Verification and Validation of Identity Preservation development procedures;
- Availability of Identity Preservation implementation procedures and work instructions;
- Availability of Identity Preservation monitoring procedures and record templates where applicable;
- Availability of Identity Preservation corrective and preventative action procedures and record templates where applicable;
- Availability of the Identity Preservation verification schedule;
- Availability of Identity Preservation verification procedures;
- Availability of the Identity Preservation validation schedule;
- Availability of Identity Preservation validation procedures;
- Completion of Identity Preservation training procedures;
- Completion of product design and development requirements related to Identity Preservation;
- Completion of process design and development requirements related to Identity Preservation;
- Completion of training for team members who have responsibilities and involvement within Identity Preservation;
- Completion of competency approval for team members who have responsibilities and involvement within

Identity Preservation.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Implementation requirements in relation to their items.

Identity Preservation Implementation Key Points

- Identity Preservation programs must be Implemented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Your Identity Preservation program must be fully implemented as per relevant documented Policies, Procedures, and Work Instructions;
- The implementation of Identity Preservation requires a commitment to the provision of resources by the Senior Management of your business;
- A properly implemented Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly implemented Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Monitoring

To review, confirm and document evidence of the implementation against documented limits.

Monitoring

Monitoring: Monitoring is the act of reviewing and confirming measurable parameters of a defined process or product status.

Monitoring requirements within food industry sectors are generally identified against limits of acceptability defined within HACCP plans, implementation procedures, and work instructions. Monitoring usually includes some element of record-keeping, which may be maintained manually or through digital systems. It is important to consider that advancements in technology have spawned many systems and processes which are self-monitored and/or self-adjusted when variances are identified. Regardless of the system used, the goal of any monitoring activity is to provide sufficient evidence that any limit of acceptability has been met.

Traditional Identity Preservation monitoring requirements include manual recording and the application of corrective actions when the results of monitoring are found to be outside acceptable limits. Corrective Actions should also generally be strongly linked to the monitoring process where applied to ensure full traceability of the applied actions.

Common monitoring activities and record formats may apply to Identity Preservation:

- Receival Records: Receival records are commonly maintained to include details of batches or lots of items received. These recorded batch or lot numbers can be used to assist in traceability activities.
- Manufacturing Records: Manufacturing records commonly contain details of the batch or lot of items as they are used.
- Packaging Records: Packaging records are commonly inclusive of the identification and traceability details of items being packaged, along with the finished packaged product batch or lot coding.
- Segregation and Labelling Checks: These confirm that identity-preserved items are stored, handled and labelled separately from non-identity-preserved items;
- Certificate of Analysis Review: Certificates are checked on receipt against the specification and the claim being made;
- Supplier Claim Status Checks: These confirm that supplier certificates, approvals and declarations remain current;
- Mass Balance Reconciliation: Quantities received, used and dispatched are reconciled to detect unexplained gains or losses;
- Dispatch Records: Dispatch records commonly include details of the customer to which finished packaged items are destined. Record formats are commonly inclusive of the batch or lot details of the product being dispatched.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Monitoring requirements in relation to their items.

You may wish to visit the Identity Preservation Templates section of haccp.com for examples of Identity Preservation documentation, record, and resource formats commonly applied within food safety and quality systems.

Identity Preservation Monitoring Key Points

- Monitoring provides real-time confirmation and evidence that your risk-based FS&Q Controls are effectively implemented;
- Identity Preservation programs must be monitored to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Monitoring of Identity Preservation must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated monitoring records for Identity Preservation must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly monitored Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly monitored Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Corrective Action and Preventative Action

To apply "real time" interventions to documented monitoring limits.

Corrective Action and Preventative Action

Corrective Action: Corrective action is mandatory action to be taken when a deviation to the Quality System occurs, particularly with a Critical Control Point.

Preventative Action: At any step in the process where a hazard has been identified, preventative action must be put into place to prevent re-occurrence.

Corrective Action and Preventative Action are implemented to ensure that any identified non-conformance issues are documented, investigated, and rectified within appropriate time frames. Corrective action is any action applied to regain control over a product, process, policy, or procedure that has been identified as being non-conforming or outside nominated limits of acceptability. Preventative action is any action applied to prevent any identified non-conformance from reoccurring.

The outcomes of corrective and preventative actions should result in regained process control after effective application. Specified corrective actions are commonly linked to the HACCP Plans and the food business certification process.

Below are Corrective Action and Preventative Action examples which may be associated with Identity Preservation related non-conformance:

- Review of the Identity Preservation policy;
- Review of Identity Preservation development procedures;
- Review of Identity Preservation implementation procedures and work instructions;
- Review of Identity Preservation monitoring procedures;
- Review of Identity Preservation corrective and preventative action procedures;
- Review of the Identity Preservation verification schedule;
- Review of Identity Preservation verification procedures;
- Review of the Identity Preservation validation schedule;
- Review of Identity Preservation validation procedures;
- Review of Identity Preservation training procedures;
- Re-training in Identity Preservation;

- Review of management review activities to include Identity Preservation as an agenda item;
- Initiation of product hold procedures where safety or quality may be compromised;
- Quarantine and investigation of suspect lots where identity or claim status cannot be confirmed;
- Investigation of the supplier of any item that fails identity verification;
- Downgrading affected product to non-identity-preserved status, or correcting labels and claims, where the claim can no longer be supported;
- Initiation of product recall or withdrawal procedures where investigations show a substantial safety and/or quality risk to released product;
- Contacting stakeholders including customers regarding any confirmed or potential Identity Preservation concerns involving their product.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Corrective Action requirements in relation to their items.

You may wish to visit the Corrective Action and Preventative Action section of haccp.com for examples of best practice applications for this food safety and quality system element.

Identity Preservation Corrective Action and Preventative Action Key Points

- The implementation of Corrective Action and Preventative Action provides confidence that your FS&Q Program is effectively implemented and that FS&Q criteria are being met;
- Where deviations or variations are observed, Corrective Action and Preventative Actions must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Corrective Action and Preventative Action of Identity Preservation must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Records of Corrective Action and Preventative Action must for Identity Preservation be maintained per relevant documented Policies, Procedures and Work Instructions;
- Proper application of Corrective Action and Preventative Action for your Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poor application of Corrective Action and Preventative Action for your Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Verification

To review and confirm documented monitoring and corrective actions against documented parameters.

Verification

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

Verification is the detailed review of all food safety and quality system elements to confirm that they are effectively developed, documented, implemented, monitored, and reviewed. All food safety and quality system elements, including documented policies, procedures, training, HACCP plans, and their operational applications must be verified on an ongoing scheduled basis. The verification process commonly includes a defined schedule for which verification activities are required, how often they are conducted, who is responsible, and detailed documented procedures for each nominated verification activity.

The general goal of an established verification process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the verification process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

The following examples of verification activities may apply to Identity Preservation:

- Review of the Identity Preservation policy;
- Review of Identity Preservation development procedures;
- Review of Identity Preservation implementation procedures and work instructions;
- Review of Identity Preservation monitoring procedures;
- Review of Identity Preservation monitoring records;
- Review of Identity Preservation corrective and preventative action procedures;
- Review of the Identity Preservation verification schedule;
- Review of Identity Preservation verification procedures;
- Review of the Identity Preservation validation schedule;
- Review of Identity Preservation validation procedures;
- Review of Identity Preservation training procedures;
- Review of Identity Preservation performance since the last review and historically;
- Analytical testing of product or process to ensure the effectiveness of Identity Preservation;
- Review of Certificates of Analysis and analytical results, such as genetic or chemical testing;
- Mass balance and traceability exercises for identity-preserved lots;
- Audit of suppliers of identity-preserved items;
- Inclusion of Identity Preservation as an agenda item within the Management Review Process.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Verification requirements in relation to their items.

You may wish to visit the Verification Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

Identity Preservation Verification Key Points

- Your verification program provides evidence that your FS&Q Controls have worked;
- Identity Preservation programs must be verified to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The verification of Identity Preservation must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated verification records for Identity Preservation must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly verified Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly verified Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Validation

To confirm the documented monitoring or procedural limits.

Validation

Validation: The process of gathering evidence to provide a scientific basis for the documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment.

Validation is the provision of evidence to support the limits of control or acceptability for food safety or quality parameters nominated within systemic elements. Limits of control or acceptability are commonly included within documented food safety and quality systems elements such as procedures, HACCP plans, and specifications.

Common sources of validation include regulatory and legislative standards, finished product specifications and customer requirements, industry codes of practice and guidelines, verified and validated research, historical

product, and process control outcomes, and analytical testing.

The general goal of an established validation process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the validation process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system. Validation activities are commonly defined within the verification schedules and procedures of established food safety and quality management systems.

The following examples may apply to validation of the limits of control or acceptability for Identity Preservation:

- Confirmation of nominated food safety and food quality control limits for Identity Preservation. These limits may apply to regulatory, industry, customer, or finished product specifications;
- Confirmation of analytical testing methods being used to confirm the effectiveness of Identity Preservation and ensure the accuracy of outcomes;
- Confirmation that testing thresholds are suitable for the claim being made, such as the limit applied for non-GMO status;
- Confirmation that changeover cleaning and segregation controls prevent mixing of identity-preserved and other items.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Validation requirements in relation to their items.

You may wish to visit the Validation Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

Identity Preservation Validation Key Points

- Your validation program provides evidence that your FS&Q Controls will work;
- Identity Preservation programs must be validated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The validation of Identity Preservation must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated validation records and supporting documentation for Identity Preservation must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly validated Identity Preservation program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly validated Identity Preservation program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Training, Competency and Resources

Skills, knowledge and competency requirements to facilitate development, documentation, implementation, monitoring, corrective action, verification and validation of every Food Safety and Quality System Element.

Skills and Knowledge

Skills and Knowledge: Skills and knowledge are attributes of human interactions commonly linked to competency within any specified job-related task.

Training and competency requirements for Identity Preservation must be ongoing, including regularly scheduled reviews to ensure the effectiveness of training and competency outcomes.

Team members who have defined responsibilities regarding Identity Preservation should have knowledge including:

- Basic Identity Preservation requirements;
- Positive outcomes of Identity Preservation;
- Negative outcomes of a lack of Identity Preservation;
- Current Identity Preservation procedures, methods, and techniques;

- General operational, corporate, and social awareness regarding Identity Preservation;
- Regulatory, industry, and customer requirements regarding Identity Preservation.

Team members who have defined responsibilities regarding Identity Preservation should have skills including:

- Competency regarding basic Identity Preservation;
- Effective application of current Identity Preservation procedures, methods, and techniques;
- The basic development, documentation, and implementation of HACCP and Prerequisite Programs within the food industry sector.

Team members who have defined responsibilities regarding Identity Preservation should have access to resources including:

- Identity Preservation training;
- Identity Preservation associations and events;
- Regulatory standards, industry and customer information and updates regarding Identity Preservation;
- Incidents within the food industry sector regarding Identity Preservation;
- Commitment to Identity Preservation by senior management;
- Suitably qualified food industry professionals with verified experience in Identity Preservation;
- Effective communication systems including email, internet, and phone through which Identity Preservation information can be sent and received within suitable timeframes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Identity Preservation Training, Competency, and Resources requirements in relation to their items.

You may wish to visit the Training, Competency, and Resources section of haccp.com for examples of best practice applications for this food safety and quality system element.

Identity Preservation Training, Skills and Knowledge Key Points

- Your Training, Skills and Knowledge program ensures all participating personnel, visitors, and contracted have the required skills and knowledge to effectively facilitate the requirements of your FS&Q Program;
- Training, Skills and Knowledge programs for Identity Preservation must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Training, Skills and Knowledge programs for Identity Preservation must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Training, Skills and Knowledge records for Identity Preservation must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Properly applied Training, Skills and Knowledge programs for Identity Preservation will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poorly applied Training, Skills and Knowledge programs for Identity Preservation will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

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