Audit Report

Global Standard Packaging Materials Issue 6: August 2019

Audit summary			
Company name	NPF Polyfilms Pvt Ltd.	BRCGS site code	1667782
Site name	NPF Polyfilms Pvt Ltd.		

Audit scope	
Scope of audit	Extrusion, printing (Gravure / CI Flexo), Slitting & Pouching of 5 & 7 layer blown film for application in food & Non-food industries using low-density Polyethylene, Linear Low-Density Polyethylene, Polypropylene, High-density polyethylene, Polyamide, Ethyl Vinyl Acetate Copolymer, pigmented Master batch, EVOH.
Exclusions from scope	None
Justification for exclusion	None

Additional modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	

Audit results			
Audit result	Certificated	Audit type	Announced
Audit grade	A	Previous audit grade	A

Number of non-conformities		
	Major against SOI of Fundamental	0
	Critical	0
	Major	0
	Minor	9

Company details			
Address	362, 362/4, 362/6, Opp Mother Teresa School Near Vadsar Airforce Station, Village: Vadsar, Taluka - Kalol, 382721, Gujarat		
Country	India	Telephone	+91 9824097622
Commercial representative Name	Samkit Shah	Email	samkit@navrangpolyfilms.com
Technical representative Name	Samkit Shah	Email	samkit@navrangpolyfilms.com

Company profile					
Plant size (square metres)	<10K sq.m	No. of employees	51-500	No. HARA Plans	4-8
Subcontracted activities	No				
Outsourced processes	No				
Other certificates held	None				
Regions exported to	North America Asia Europe Africa Choose a region				
Major changes or auditor observations since last BRCGS audit	None				
Company description	NPF Polyfilms is a group company of Navrang Polyfilms. Present unit is located in Wadsal in the outskirts of Ahmedabad. Facility is a permanent structure comprising of a combination of RCC and girder and frame with a built-up area of 4900 square meters. Company operates with 100 personnel per shift in two shifts. The operation comprises of co-extrusion of multilayer plastic-based films by blowing process and then conversion in to printed film and pouch or bag making. The product is used in food and non-food industries. The production is 540 MT Per month of multilayered printed flexible plastics in various pouch and roll forms. The company sells products to markets such as USA, Europe, Africa and Middle East. The site does not wish to disclose their turn over and does not use any Logo in the product				

	or packaging material.

Product and process characteristics

Manufacturing Categories (Glass Paper Metal Rigid plastic Flexible plastic Other materials Print processes Chemical processes)	05 - Flexible plastics 07 - Print processes Category Category Category Category
Products in production at the time of the audit	Extrusion of 7R12, 5R50 Milk film, Pouching job P05/878, P0J/877, Printing PJ/1248

Audit duration details

Finish date	2020-11-03		
Re-audit due date	2021-11-02	Previous audit date	2019-05-14
On-site duration	16 hours	Duration of production facility inspection	8 hours
Reasons for deviation from typical or expected audit duration	None		
Next audit type selected	Announced		

Audit duration per day

Audit days	Date	Audit start time	Audit finish time
1 (start date)	2020-11-02	09:30	19:00
2	2020-11-03	09:30	17:00

Auditor information

Auditor number	Auditor Name	Role
007046	Harshad Karulkar	Lead Auditor
N/A		

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.8) Name / Job Title	Opening meeting	Site inspection	Procedure review	Closing meeting
Samkit Shah - Director	X	X	X	X
Darshan Shah - Director	X	X	X	X
Kenil Patel - Shift in charge	X	X	X	X
Hitendra Parmar - Extrusion	X	X	X	X
Himmat Rajput - Roto printing	X	X	X	X
Prem Rana - Flexo in charge	X	X	X	X
Nilam Shah - Admin in charge	X			X
Dipali Shah - HR in charge	X			X

	GFSI Audit History	
Date	Scheme/Standard	Announced/Unannounced

Non-Conformity Summary

Major non-conformity against statement of intent of a fundamental requirement				
No.	Requirement ref.	Details of non-conformity	Critical or Major?	Anticipated re-audit date

Critical			
No.	Clause.	Details of non-conformity	Anticipated re-audit date

Major							
No.	Clause	Details of non-conformity	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date reviewed	Reviewed by

Minor

No.	Clause	Details of non-conformity	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date reviewed	Reviewed by
1	2.1.2	Two of the team members could not adequately demonstrate their knowledge on HACCP principles during verbal discussion in audit.	Refresher training has been provided to all the team members on HACCP Principles	Training calendar has been modified to include - method of training & training effectiveness evaluation. Training calendar shall also include period of evaluation from the date of training imparted.	HACCP team members were imparted with awareness training on HACCP principles as per requirements of BRCGS Packaging - Issue 06 but training effectiveness was not carried out as criteria for training effectiveness was not defined.	2020-11-25	Harshad Karulkar
2	2.2.5	The most recent onsite verification of process flow diagram was not evident.	On-site verification of process flow diagram has been done again by all members of HACCP team	On-site verification flow diagram has been modified to provide the provision for dates of verification. HACCP team members has been imparted with refresher training on requirements of on-site verification of process flow diagram	On-site process flow diagram was carried out by HACCP team members but there was no provision for dated, so it was not adequately clear regarding the on-site verification of process flow diagram	2020-11-25	Harshad Karulkar
3	3.2.1	Identification of few of the document formats being used on site such as material composition chart, quality check report pouching, printing data QC sheet was not evident.	Identification of few of the document formats being used on site such as material composition chart, quality check report pouching, printing data QC sheet has been provided with document identification number.	Master list of Formats has been modified to include all the formats which were being used but not part of Master list of Formats. Supervisors & HODs has been imparted with refresher training on requirements of Control of Documents.	These formats (e.g. Material composition chart, quality check report pouching, printing data QC sheet etc.) being used were actually filled up as live data by operators & at the end of the shift, same data were transferred in ERP by supervisor. Supervisor & HODs were lacking the awareness that, all the formats being used by site shall be part of document	2020-11-25	Harshad Karulkar

					control system & included in Master list of Formats.		
4	3.11.2	Identification of various resin grades on the holding bins before their feeding to 7 layer blown film line B was not clear.	Identification of resin grades on the holding bins before their feeding to 7 layer blown film line B has been displayed / provided	Provision has been made on holding bins of Resins for actual display / identification of Resin grade being feed. Resin loading helpers as well as Extruder operator & Shift engineer has been imparted with training on protocol to be followed for resin identification as current & live.	Resin loading in holding bin was done by resin loading helpers as per resin loading sheet given by production supervisor, but there was no provision on holding bins for identification for resin grade	2020-11-25	Harshad Karulkar
5	4.1.3	External areas had some storage of waste material such as drums and other waste material not cleared away.	External areas has been cleared from storage of waste material such as drums and other waste material.	Dedicated area has been identified & demarked as Waste storage area for storage of all types of waste. Production & Store personnel has been provided with training on storage practices of waste materials at newly designated waste storage area	Identified waste materials such as drums & other waste materials were lying in external area due to recently completed construction activities & no formal area has been defined/ determined for storage of waste materials.	2020-11-25	Harshad Karulkar
6	4.2.1	Wall corners behind the resin feeding area of 7 layer B was not maintained in good condition.	Wall corners behind the resin feeding area of 7 layer B has been repaired to good condition.	1 feet distance marking has been done across the walls to prevent any material stored adjacent to the wall as well ensuring daily adequate cleaning & notice any damages to the floors/walls. Daily sanitation & hygiene monitoring record format has been modified to incorporate the check points of monitoring of walls corners condition & safe distance of material	Walls corners were accidentally damaged due to material movement trolley but were not noticed due to covered by material pallets. Monitoring of walls corners damage as well as keeping distance from walls was also not part of Daily sanitation & hygiene monitoring record	2020-11-25	Harshad Karulkar

				storage from the walls. Production operators & GMP monitoring personnel has been imparted with refresher training on revised protocol of Daily sanitation & hygiene monitoring			
7	4.8.5	The microbiological environmental monitoring being carried out does not define the sampling protocol, frequency of tests, test methods of the Identified sample locations.	The microbiological environmental monitoring has been modified to include sampling protocol, frequency of tests, test methods of the Identified sample locations.	All HODs who are also part of HARM team has been imparted with training on interpretation requirements of microbiological environmental monitoring	Requirements of the clause - Microbial environmental monitoring was not adequately understood.	2020-11-25	Harshad Karulkar
8	6.2.1	Jewellery control was not well implemented as few of the personnel were found to be using hand threads.	Hand thread has been removed from the identified personnel.	Monitoring & compliance of hygiene policy has been shifted from main gate to each change room & security personnel has been deployed at each security room Every employees including Security personnel have been imparted with refresher training on Hygiene policy requirements	Frisking of each employee is being carried out at main security gate as per Hygiene policy but due to inadequate controls, this may have been unnoticed by security personnel.	2020-11-25	Harshad Karulkar
9	6.5.7	Details of the contracted laundry service provider was not available on site.	Details of the contracted laundry service provider has been made available on site.	Chief accountant, who is also responsible for purchase process has been assigned responsibility for record keeping of all external providers' agreement / contracts. including All 3rd party contract (e.g.	Laundry contract was made & in place but it was not properly filed, so it was not traceable on the date of audit. This was due to improper filing of records & not clearly defined responsibilities for record keeping of all external	2020-11-25	Harshad Karulkar

				Laundry, Pest control, Transportation, Quality & Product safety management consultant, Waste management etc.). All contract has been filed in Purchase records file Procedure for purchase has been modified to incorporate above requirements. Process owners of Purchase, HR & admin, Transportation has been imparted with refresher training on revised protocol for record keeping of 3rd party contracts.	providers' agreement / contracts.		

Comments on non-conformities - not tagged, just free text. This is to explain where a large number of NCs have been raised without a major

Additional Modules/Head Office Non-Conformity Summary Sheet

Critical			
No.	Clause	Details of non-conformity	Anticipated re-audit date

Major							
No.	Clause	Details of non-conformity	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date reviewed	Reviewed by

Minor							
No.	Clause	Details of non-conformity	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date reviewed	Reviewed by

Detailed Section

1.	Senior management commitment
1.1	Senior management commitment and continual improvement
	Commitment of senior management is evident through provision of good infrastructure, resources, site management & activities supporting implementation of the standard. Company has established a Quality and Product Safety Policy Annexure 1. This is part of Product safety management system manual GSFS/M/01. Quality policy is reviewed on yearly basis during Management Review Meetings. Policy is communicated by displaying it in locations like change room, entry point, production floor etc. Site is in process of developing various aspects related to the Food safety quality culture plan. Company has established detailed objectives previous year which are continued this year after some revision. These are as follows, The current objectives are as follows; • Production department no deviation in CCP; • Production – extrusion department to have less than 3% wastage; • Printing to have less than 1.3% wastage; • Slitting to have less than 5.35% wastage; • Max 2 customer complaints due to other factors per 6 months; • Sales (Customer satisfaction index to be 85 status 101%) • HR (Min 11 training per month related to food and health safety awareness status 82% achieved); • Store (minimal scrap during inventory & storage) which is also achieved; • Maintenance to ensure not more than 120 hours of breakdown each month actually found 111 hours as production has ramped up. • Purchase (vendor rating to be 100 achieved 99.98). Site has identified all departments handling individual functions. Meeting each country specific or legal or customer requirement as applicable is managed by the Marketing department managed by the Director. Directors are actively involved in participation of packaging industry associations such as CIPET & GSPMA. Company also subscribes to Scientific journals for getting legal updates. Current original copy of standard is available in electronic format. Current original copy of standard is available in soft form. The site underwent risk assessment in May 2020 and next re-audit due date is 25th Nov and audit is conducted on 2 / 3 Nov 2020. Both Directors and site relevant personnel attended both opening and closing meetings along with Production Head. Functional heads were available as and when required during the audit. All the 6 Non-conformities of the previous audits are now closed appropriately.
1.2	Management review
	Site's senior management reviews the product safety and quality management system twice in a year. Company has s system of collecting information from various department and reviewing them on regularly on monthly basis. Company's frequency of Management review meeting is once in 6 months. Last MRM was conducted on 17th Oct 2020 and previous to that on 15th May 2020. This was attended by Director Sales & Director Operations & departments totally with 6 members. The review meeting involved discussion on aspects such as;

1. Follow up action items from previous management review meeting (no pending action)

2. Results of Internal, second – Party & Third – party Audits performed during the time period (Internal, External, Customer, Compliance etc.) External expert (Mr. Shashank Sheth) conducted IQA in September 2020 as per IQA schedule based on risk assessment. Effectiveness of the corrective action found adequate till date. However, audit for the other processes scheduled in April, June & July could not be carried out due to COVID19 pandemic. There were 7 NCs were observed which had been actioned effectively.

3. Customer performance indicator, complaints & feedback (surveys, concerns, complaints, positives, customer visits). Customer feedbacks are being taken once/year. 7 Customer feedbacks collected for the period of Apr'19 to March'20 & observed 86 % against target of 85%. Continued orders from existing customers in place, introduction of new customers are overall indicator of improved customer satisfaction & market reputation. There are 2 customer complaints received so far since last MRM and have been effectively closed.

4. Review of Hazard & Risk management (HARM) system. HARM plan has been last modified dated 05.02.2020 as per requirements of BRCGS - Packaging, Issue 06. There has been no change in process flow or processing steps or raw material or packing material or introduction of any new hazard etc.

5. Impact of any applicable legislative & certification scheme changes. There has been no changes or updates in applicable legal requirements such as EC 10/2011 referring to www.ec.europa website. No additional legislation related to Product safety in line with our products so far found. All the Raw material being used meets all applicable legal requirements for Indian, EU & USFDA legislations. RD/05 found updated for all current legislation related to Product safety of IS, USFDA & EC regulations based on TDS received from each RM supplier. Migration test as per EC 10/2011 has been carried out in December 2019 as per yearly frequency

6. Incidents, corrective actions, out of specification results & non-conforming products. Product safety incidents (Actual or potential for product contamination) due to documented scenario such as glass breakage, metal contamination etc., Corrective actions report for product & process NCs, Inspection & testing results at Incoming, In-process & customer returned if any. Internal monitoring records of Glass breakage, Blade & cutter integrity indicates foreign matter contamination control. Internal rejections (Process waste, set up waste, product rejection etc.) are found well within norms & set objectives. Mock recall frequency is yearly & last mock recall was carried out on 30.04.2020 & found satisfactory.

7. Resources requirements. Based on the review of current business scenario & customer requirements including feedback as well as complaints, further modification is planned as below. Competence mapping & Training need identification has been carried out as per newly established Personal competence matrix & Training need identification matrix.

8. Quality & Product safety objectives (9 nos.) reviewed against set parameters. (Refer Quality & Product safety objective data sheet from Oct'19 to March'20. Similarly, for the next period of review (Oct'19 to March'20) no objectives has been revised & all objectives remains unchanged. The previous objectives are as follows; Production department no deviation in CCP, Quality- zero rejections due to mechanical properties, less than 1 % rejections due to shade variation. Max 2 customer complaints due to other factors per 6 months, Sales (Customer satisfaction index to be 85 status 98%) HR (Min 11 training per month related to food and health safety awareness status 9). Store (minimal scrap during inventory & storage which is also achieved, Maintenance to ensure not more than 30 hours of breakdown each month actually found 24.89

	hours. Purchase (vendor rating to be 100 achieved 99.98). In every management review meeting held 6 months the objectives are revised. The current objectives are as follows; Production department no deviation in CCP, Production – extrusion department to have less than 3% wastage. Printing to have less than 1.3% wastage. Slitting to have less than 5.35% wastage. Max 2 customer complaints due to other factors per 6 months, Sales (Customer satisfaction index to be 85 status 101%) HR (Min 11 training per month related to food and health safety awareness status 82% achieved). Store (minimal scrap during inventory & storage which is also achieved, Maintenance to ensure not more than 120 hours of breakdown each month actually found 111 hours as production has ramped up. Purchase (vendor rating to be 100 achieved 99.98). 9. Effectiveness of Product defence (TACCP) and product fraud prevention plans (VACCP) 10. Adequacy and awareness of Various Policies (Quality & Product Safety Policy, PRP Polices etc.) 11. Usage & compliance of BRCGS Logo (V-card, Website, Letterhead, Email signature, Product packaging etc.) The MRM minutes are documented and details reflect the decisions taken. Company collates operational details in the form of monthly meetings and same is communicated to top management. This is recorded in the form of Management review meeting F/SYS/04.
1.3	Organisational structure, responsibilities and management authority
	Company has defined clear structure of organization and also rolls and responsibilities are found to be clearly defined considering product safety, legality and regulatory compliance. Company has an organization chart demonstrating the structure of the company & positions. Ref. Organizational Chart Annex 02 Food Safety Management System Manual. The organization chart identifies clear communication lines for each of the 5 departments under the Director. Operations Director is the FSTL. Responsibilities pertaining to quality are clearly documented as seen in case of quality in charge who is also deputy team leader reports to Director operations. Work instructions are found to be documented and displayed at various work locations. Responsibilities are communicated to the employees in the form of job descriptions and induction trainings. Acknowledgement of job responsibilities are maintained.
Non-applicable clauses	

2.	**Hazard and risk management**
2.1	Hazard and risk management team
	Site has a multidisciplinary team of 7 members who have developed hazard and risk management system and is involved in its implementation. It comprises members from various functions like senior management, representatives from extrusion process, printing, maintenance, stores and dispatch as well as external experts. Refer Product Safety Team / HARM Team GSFS/M/02 page 6 – 8 of HARM Manual GSFS/M/02.

	Mr. Darshan Shah is team Leader with 15 years of experience in manufacturing & quality aspects with training on HACCP from external experts and Hitendra Vanzara Shift Engineer Production and QC. Team is able to demonstrate competence of HACCP principles except few personnel due to which a nonconformity has been raised. **One minor NC 1 has been raised against 2.1.2; Two of the team members could not adequately demonstrate their knowledge on HACCP principles during verbal discussion in audit.**
2.2	Hazard analysis and risk assessment
	Hazard and risk management system is found to be developed and implemented by a 6-member HACCP team to manage risks associated with product safety, quality and legality. This is documented in terms of HARM Manual GSFS/M/02. The scope of the hazard and risk analysis is manufacturing of flexible packaging using individual processes of blown film extrusion, printing, slitting & pouching. There has been no major changes in the processes as indicated above. There are some equipment added in but no new process step introduced. All potential hazards are identified & considered i.e. Physical foreign materials, metal, thread, wood, trim pieces, glass, brittle plastics and other quality related aspects. Chemicals, oil, grease, inks, bond strength, barrier properties, odour, moisture, possible migration of process chemicals are considered. Team has collated their related industry related experience to assess possible hazards applicable. Some more aspects related to functional integrity or product safety or possible points of contamination are analysed at relevant process steps. All biological, physical, chemical, and bacteriological hazards are considered. Refer Hazard Analysis worksheet. All possible hazards & risk have been considered for Biological (due to cross contamination and infestation, personnel, packaging), Chemical (odour, transfer from inks and migration) & Physical hazards dirt and dust. There are some defects which may lead to quality defects & are over and above physical, chemical, biological defects which are important for customer. These are part of online quality monitoring system conducted immediately. Awareness about hazards associated with every step was verified. All possible hazards & risk have been considered for Biological (due to cross contamination and infestation), Chemical (heavy metals) & Physical (foreign particles) hazards. All hazards have been identified and analysed based on historical data, relevant code of practices, legislative and regulatory requirements. Customer requirements are also considered for hazard analysis. Consideration of new hazards such as malicious intervention and raw material fraud are also discussed as part of the Hazard analysis Extrusion, printing, slitting, pouching. Refer Hazard Analysis in HARM Manual GSFS/M/02. Product description is detailed and developed to covers various aspects related to flexible films including individual process such as blowing of 5 & 7 layer of PE based films, printing, slitting, pouching use of inks. Development of films is based on customer requirements and application. This involves composition, ingredients, physical mechanical properties, chemical properties, barrier, processing activity, storage, labelling and legal compliance. There is no recycling involved in the process. Refer to Product description Unprinted polyfilms in roll and pouch form, printed polyfilms in roll and pouch form page 10-15 of HACCP Manual covering 14 different requirements. Intended use for the products is mostly for food but also non-food. Food applications are milk products, meat, bakery, oils, dried products as an example. Company carries out processes of blown film manufacture through extrusion followed by printing slitting and packing of slit rolls or pouching as applicable. A flow diagram is developed which includes all the processing steps within the scope. There is process flow diagram covering each process and its link in the final production activity. Company may produce plain film or printed film which may be in both roll form or pouch form. On site verification of process flow diagram was done on earlier however the most recent onsite verification was not available leading to a minor NC as below. Refer to Manufacturing process and process flow diagram on page 16 of HACCP Manual

	M/01 & Art work approval process flow chart page 17. The HACCP team has considered the control measures necessary to eliminate or reduce the hazard to acceptable levels. Consideration is given to using more than one control measure or controls at various subsequent points of process. The monitoring method for each hazard is determined through good pre-requisite programs, facility control and as well identified points during each of the processes of printing, extrusion, slitting, doctoring and packing. A detailed risk analysis is documented in the form of Hazard Analysis table. Company has identified indirect controls through Pre-requisite programs and direct controls through CCP. Company has identified 2 CCP in terms of CCP – 01 is at Blown Film process which is Corona treatment as per required range dyne level of minimum 38. CCP 1 it is minimum 38 dynes per square cm. CCP2 it is complete removal of earlier lots without any possible mixing CCP limits have been defined for each. Ref Doc: HACCP Plan. Monitoring system has been defined for each CCP. All the monitoring is visual and recording is undertaken for all the values as identified in the limits.
	Could verify the monitoring of CCP – 01 is at Blown Film process which is Corona treatment as per required range dyne level of minimum 38 for work order EX/1319 which was run on 2 Nov at night time and ERP data mentions the average dyne value for each roll 205L003348 where the value found to be 40 recorded in Extrusion receipt. This is recorded in ERP system online for each roll. For CCP2 and its monitoring the site maintained in ERP system during unloading of each roll. In case of job order no PJ/1249 for roll no 205L003351 printed was cleared of previous job PJ/1243 as well as 7 different aspects (balance rolls / ink / master shade card / cylinder plates /film types / job change waste / designated place assigned) are checked. colour shade and text matter. Corrective actions are found to be defined for each CCP, for CCP 1 it is quarantine the product and discover the possibility of retreating the material and for CCP 2 it is hold the material and resort for print checks. The risk management team has considered the process steps and reviewed the process last such review was found to be done in 5.2.2020. **One minor NC has been raised against 2.2.5 ; The most recent onsite verification of process flow diagram was not evident.**
Non-applicable clauses	

3.	Product safety and quality management
3.1	Product safety and quality management system
	Company has documented all the processes and procedures in terms of individual manuals which are controlled and accessible. Company has documented various Standard operating procedures, work instructions, pre-requisite programs and forms. Every respective department is provided control copies of relevant documents respective to their activities. Master list of procedures and

	formats is available with management representative along with one set of complete documentation. Company manages various manuals such as Quality and product safety manual GSFS/M/01 this provides references to BRC requirements and how they are met. HARM Manual GSFS/M02 Rev 03 4-2-2020, Master list of formats and records F/SYS/02 dated 16.1.20.
3.2	Document control
	Effective document control system is in place which ensures use of current version of documents. Company has documented a SYS/PRO/01 Procedure for Document & Data Control which describes the system of identification as part of SOP manual. A full list documents is available in terms of Master List cum Distribution list of documents F-SYS-01 is in place. Also included are each Annexure, SOP, HACCP & BRC Manual. Lately site has introduced a specific ERP related system which all the manufacturing data of inputs and quality are updated online and many of the process log books are online information which can be tracked. However few of the hard copy formats were not identified correctly as per the sites document identification system leading to a minor NC as below. All online information is backed up regularly. Systems are password protected to avoid unauthorized access. **One minor NC 3 has been raised against 3.2.1; Identification of few of the document formats being used on site such as material composition chart, quality check report pouching, printing data QC sheet was not evident.**
3.3	Record keeping
	Hard copies of records are maintained at site and electronic records are backed up monthly. Records are legible and genuine and authorized by respective department heads. Procedure for Control of records SYS/PRO/02 this also identifies the master list of formats and records F/SYS/02 and requirement of controlling of the quality records. Details such as format number, title, revision no, kind of record, retention period, disposition and responsibility are defined. Retention period of individual records is identified on master list of records; retention period varies from associated record of each departments which is mostly 3 years however usable life of product as declared is only 3 months. Company may review the requirement of record maintenance. Master list of formats and records F/SYS/02 dated 16.1.20.
3.4	Specifications
	Company manufactures coextruded films for printing and pouching and bag making applications. The coextruded films are produced as an alternative to laminated film applications. Specifications for all materials handled on site including raw materials, work in process material, finished goods are sufficiently documented. Company has established basic specifications for substrate multilayer film which are developed for specific functions. These may be printed or plain and may be converted in to pouches or rolls by using. inks or other inputs which can be used in the manufacturing process. All the inputs are used in combination with specific process to be converted into multilayer, printed/unprinted material of identified thickness, dimensions and other physical parameters.

	Functionality of these products is specific to each customer's requirement and application. Based on the information received from the customer technical aspects are developed and documented in terms of a Technical specification sheet which considers all the details of materials and process to be used for that product. A technical specification sheet covers the process and substrate requirements. This could be developed on the basis of suggested application from the customer. In the last 1 year the site has converted all product specific information in to an online software which is available at each process steps and carries all the product related information. Mostly site develops own technical specification for a customer and then it undergoes trial at the customers end. A technical specification sheet was received from a customer for Poly film Live lite milk which. Was revised from earlier specs with remarks included print related adding central region, average thickness revised from 50 to 52 micron. Specification include description of material, material construction, thickness, length, width, core dia, density, eyemark, GSM, dart impact strength, seal strength, film form, joints, tensile strength, elongation, coefficient, drop test. The site transfers this required information is converted in to ERP based available information under milk film with specifying 13 aspects. Over a period of time site has developed an inventory of 100 plus product combinations for particular applications and customers. A technical specification sheet used to be maintained now site has converted all of this into online system. Library of all product specification is now a part of Party wise Brand master which has almost 2300 plus SKU specifications. As a result of direct process monitoring and quality checks a certificate of analysis (COA) is generated covering various parameters such as width, opacity, thickness, GSM, Coef inner / outer static and kinetic, surface treatment, dart impact, hot tack, tensile strength MD / TD , Elongation MD / TD, Print defects and so on. Could verify a COA for product Shrink Film NAT against packing list PL/1783. This covered adherence to various parameters as identified in the quality plan. Company provides a certificate of analysis cum declaration of compliance to the packaging material users. This is based on specific needs from customers and covers declaration of content, provided in terms of certificate of analysis. Company routinely conducts product contact migration test to check possible impact on material. Currently the site has again conducted overall migration test and specific migration test through report MUM/001770/202 dated 14.9.2020 for Milk Packaging Ghee packaging LDPE blend film for Overall migration EU 10/2011 and Specific migration of heavy metals. Company reviews base specification for all combinations being offered before execution of an order which details type of changes which may be needed. There have been no changes as such last review was in 30th Oct in an oil flexible film. All the specifications are maintained in the form of soft and hard copy.
3.5	Internal audits
	Company has developed a system of internal audits for checking the application of this standard. The internal audit is conducted by inter department personnel overseen MR function. A system procedure for internal audit SOP 20 is established to provide an overview of system of conducting audits. Company conducts Internal Audits 7 times in a year in 2020. The areas identified are sales and marketing, customer feedback, senior management, production, quality control, specification, testing, product release, Raw material and warehouse management, procurement, housekeeping, plant sanitation, maintenance, FSTL systems. Ref Internal Audit 2020 & Internal Audit risk assessment Year 2020. Internal audit program is found to be implemented. Site has taken services of external consultant who ensure necessary systems are developed but implemented by site. An internal audit was

	conducted of HR & Admin department on 26 Sept 20 this had a minor NC which was closed using Internal audit NC report. An internal audit schedule & plan F/SYS/05 is also maintained for the audits. The audits were carried out by 3 identified audit team members which includes external consultant. All internal team members are trained by consultant. However, audit for the other processes scheduled in April, June & July could not be carried out due to COVID19 pandemic. There were 7 NCs were observed which had been actioned effectively. A programme of documented inspections to ensure that the factory environment is in good condition is maintained in the form of GMP inspection record F/HR/19 this covers 19 different areas.
3.6	Corrective and preventive action
	Site has documented a corrective preventive action procedure SYS/PRO/05 which identifies sources of non-conformances from process NC, CCP monitoring, internal audit NC, system NC monitoring, customer complaints, problem identification. The implementation of this is in the form of internal audit NC report F/SYS/10 and non-conformance and corrective action report F/SYS/11.
3.7	Supplier approval and performance monitoring
	Company has established procedure for purchase PRO/PUR/01. The procedure identifies the criteria selection of suppliers. Company uses various resin-based inputs such as low-density Polyethylene, Linear Low-Density Polyethylene, Polypropylene, High-density polyethylene, Polyamide, Ethyl Vinyl Acetate Copolymer, pigmented Master batch, EVOH. The criteria of procuring material from specific supplier is decoded by the Directors which is based on specification such as MFI value, quantity availability and segmented supply and finally price. Site is mostly importing all resins (90%), and locally procuring ink and master batches. These are the basic criteria of procurement. These resins are converted in to multi-layered film of 5 or 7 layers plain or printed our pouches undergoing various processes. Other purchases are inks or spares or other inputs. A list of approved suppliers (RM/PM/Service providers) F/PUR/02 is maintained which identifies 67 input suppliers and 12 different service providers and 5 packaging material providers. Further to the above selection of a supplier is also based on supplier's market reputation, company' experience in dealing and supplier questionnaire as well as supplier facility inspection as identified & applicable. Once the purchases are initiated the quality-based checks are undertaken or certificates of analysis or declaration of compliances are collected. Once the purchases are regularised assessment is conducted based on quality, delivery, food safety attributes and facility visit. Site has added in some new suppliers they have undergone a trial process and subsequent approval; In this case a trial was undertaken from 6th June 2020. One of the new supplier of hot melt adhesive who has been assessed. A supplier assessment form F/PUR/01 is required to be filled following which a supplier self-assessment questionnaire F/PUR/07 seen maintained covering some aspects related to product, purchase process, factory environment, pest control, environment, storage, HACCP. Supplier VACCP & TACCP Declaration F-PUR-08 is also now introduced considering new requirements. Evaluation for performance against quality, quantity, delivery is assigned & a % score is derived. Company maintains a raw material and packing material supplier performance monitoring record F/PUR/04. Each consignment is tracked for criteria as identified as a score. Lot wise tracking is maintained. Raw material resin, MB, PM performance monitoring register F/PUR/03 is maintained categorised for food safety rating, quality, delivery and resultant grades A / B/ C. Most of the

	suppliers are indicated to have scored high rating. This assessment is detailed and considers material procured, no of lots received, rating on the basis of rejections, food safety compliance, quality, delivery, food safety and overall results. Exceptions are defined for purchases which are done from new suppliers as an emergency on approval of the management.
3.8	Product authenticity, claims and chain of custody
	Site procures raw materials various plastic based resins such as LDPE, LLDPE, HDPE, MLLDPE, Nylon, Master batch, colour MB, UV MB and other additives such as Slip additive, tie resin, bynel , PPA which have specific purposes in making coextruded films. All raw material are plastic based and have specific functional end use in final films e. These are procured against certificate of compliance. Site has documented Raw material vulnerability assessment and its control points VACCP RD/24 which covers assessment against history, emerging concerns, price fluctuations, trading properties, geographic origins, complexity of supply chains ease of access, price, size of market. The output identified is low significance of this happening Ref vulnerability assessment and its control points VACCP RD/24.
3.9	Management of subcontracted activities and outsourced processes
	Site does not conduct any outsourced process activities. Clause 3.9 is not applicable.
3.10	Management of suppliers of services
	Some of the services such as transport, pest control, external testing labs, calibration, transport, internal audit and health check-up are taken from service providers. Company has documented procedure for purchase (PRO/PUR01) which defines the criteria for selection of service providers followed by criteria for evaluation. Company uses the services for Pest control (PCI), Calibration (Accurate Lab), Testing Lab (GEOCHEM),. There are totally 8 identified service providers. Alphaflex (printing plates), CIPET (Product testing), DSH (Testing machine calibration), Gaurav logistics (transporter). Criteria for selection & approval is defined for each category in the form of requirements such as Legal approval, transporter vehicles requirements, Registration against relevant authority, Labs to have 17025 certifications. Evaluation to be done by rating service delivery parameters and observing impact of service in case of pest and transport. In case testing by turnaround time and so on. Company maintains agreement with Pest control, laundry, transport and testing cum calibration services.
3.11	Traceability
	Site manufactures coextruded multilayer films which could be plain, printed or pouched. Company has established traceability system from raw material to the finished goods through individual process steps. Company monitors consumption of inputs resin / inks and tracks the production this is done by close monitoring of individual inputs and recording ability to trace them. Company produces material as per customer specifications and offers certain product spec films. The enter process is planned as per quantity required.

	All information pertaining to use of inputs is captured by assigning a job order / work order no. All the materials required for execution of that work order are identified at individual process stage. Materials are assigned by the stores for execution at each process. This year site has completely moved to online ERP data system and tracking of job execution is entered directly by allotting information online by the computer stations provided online. Manufacturing steps broadly are extrusion, slitting, printing, pouching as applicable. Extrusion is of resins by using identified materials such as LDPE, LLDEP, , PA/PE, EVOH etc Subsequent steps as applicable are printing, slitting the material and finally pouching / bag making. One or many combinations of processes could be conducted. At each step the job order captures process requirements and individual process log books capture rolls, or resin provided. Traceability of all inputs is available and maintained. Identification of material is adequate and can be verified through the testing of traceability internally or during the audit. Few of the bins supplying resins of specific grades were not adequately identified leading to a minor NC as below. Own check of traceability was conducted on 25th July 2020 of product Rajgiri 200GM 135X195. Pouch quantity 42500 Date of Production 10.07.2020. 5 Rolls of 20SLA000621 / 20SLA000629 / 20SLA000626 /20SLA000627/ 20SLA000628 were used in pouch making and the input to these roll were 5 types of resin grades C40 NYLON, 825 TIE LAYER, 1018 N LLDPE NON-SLIP, 1018 H LLDPE LOTRENE 2427 LDPE SLIP from 5 lots191129S, C00240152, 2004QT038, 2005QTO10, ZA2674Y03 Final product may be a roll or pouch packed in boxes. They are identified with a label such as follows. Name of customer (Amico), box no (20CBO11296), description of material Grey mail bag, date of production 27.10.20, size of bag 305 x 406. The number 20CBO11296 provides further link through use of the installed software. During the audit traceability can be verified for product Lip and tape bag 9.25 X 12, packed on 20CB007370 packing list no PLP/743 comprising of 120000 bags in 60 boxes. Selected traceability of 17 boxes (20CB07370 - 7387). The process steps were extrusion, printing, slitting, bag making. These were made against sales order 4521. The company references were as follows extrusion process EX/651 - 2 Rolls 5L1753 & 5L1754. 5L1753 was used for these 17 boxes. Flexo printing PJ 591 Printed roll was CIF2079, This underwent slitting job order 1039 slit in to SLD1983. This was used in to 17 boxes pouches 340000 pouches. Extruded roll SL1753 was produced using input resin such as 1018H LLDPE, 310 LDPE, 5010 HDPE, FB2230 1018MK was used and can be traced to lot number. Also could verify traceability of AMICO PACKAGING PF:1209-20-1 BLACK AND GREY Plain Pouch made between 18 - 25th Oct and can be traced to extruded rolls along with the input material such as 205L003108 - 1018 H LLDPE LOTRENE, 205L003109 - 1018 N LLDPE NON-SLIP205L003110 and 0499 GREY MASTER BATCH, 205L003111 -310 LDPE along with the lot numbers. There is no rework applicable clause 3.11.5 is not applicable. **One minor NC 4 has been raised against 3.11.2; Identification of various resin grades on the holding bins before their feeding to 7 layer blown film line B was not clear.**
3.12	Complaint handling
	Company manages all issues regarding customer complaints by involvement of management at

	each stage and redressal of all issues. Complaint handling process as a part of Procedure for customer complaints PRO/SA/03 is documented. If there are complaints then they are recorded by Director / marketing department and discussed for further investigation. So far there is one major complaint regarding hot melt adhesive glue which is under discussion between site and their customer and was expected due to wrong grade of the glue. Customer complaint form F/SA/03 was formed to be maintained for the consignment 17th July 2020. There are no other complaints other than these.
3.13	Management of product withdrawals, and incidents and product recalls
	The site has a team of key persons supported by a guidance document to handle possible incidents of varying impacts and manage safety of products or it's contamination. Company has documented procedure for product withdrawal & recall PSMS/PRO/04. Procedure identifies withdrawal team of 5 members their roles and responsibilities and communication plan. The procedure is reviewed periodically and amended when necessary. A responsibility matrix of product withdrawal / recall team is clearly documented. There are 12 different activity steps identified and responsibility of relevant member identified. Withdrawal procedure is found to be capable of being operated & considers notification to the customers and government authorities if needed. However there has never been an actual situation.[1 SEP]Product safety team leader is given responsibility of root cause analysis and preventive actions. Company has provided written guidance in the form of procedure for Product safety incident management PSMS/PRO/03. It identifies 15 types of incidents related to personnel, equipment and situations. Activity required to manage incidents is defined in this procedure. Company provides products to the customer who use it as final packaging at their end therefore in principle only withdrawal is applicable in this scenario and not recall. But company's team maintains readiness to react in both situations if required. There has been no real withdrawal however procedures states that company shall provide complete traceability information as and when required. Product withdrawal testing frequency is defined to be annual. Product withdrawal procedure is found to be tested on 30.04.2020 for product DOODHVALE PANEER 200 GM 145X200 - 10000 Pouches Invoice number - 98/20-21, dated 23.04.2020 for a lot of 10,000 pouches material sent to a customer and response was collected on the same day for consumption of part lot.
Non-applicable clauses	3.7.7, 3.9, 3.11.5

4.	Site Standards
4.1	External standards
	The unit is located in a plot of 8400 square meters and present built up area is 4300 square meters which is maintained to appropriate standards by effective control on the processes to minimize risk and production of safe and legal products. Site has expanded from the last year and has now 3 buildings. Site is located in in Vadsar area in the outskirts of Ahmedabad sufficiently demarcated. The external

	areas are well maintained and concretised. The building fabric is maintained to minimise potential for pest entry or ingress of water. Combination of girder and frame and RCC construction is provided. A clean and unobstructed area is provided along one of the wall of the buildings used for production and/or storage. External drainage is adequate to manage possible water flow. External areas had a lot of discarded an to be used drums which led to a minor NC as below. External storage of raw materials is not practiced. Clause 4.1.5 is not applicable. **One minor NC 5 has been raised against 4.1.3; External areas had some storage of waste material such as drums and other waste material not cleared away.**
4.2	Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas
	Site consists of 3 separate units 1 housing all the 3 blown film extrusion lines, other having flexo printing and resin storage and a new unit having pouching operations. Each of the buildings are comprised of RCC structure and panel and girder and frame structure provided for the intended purpose and designed, constructed, maintained for effective control to the risk of product contamination. Walls and Floors are maintained in good condition and facilitate cleaning. There is no suspended ceilings are maintained to prevent possible contamination. A section behind the extrusion line was not adequately maintained leading to a minor NC as below. There is no requirement to provide internal drains clause 4.2.3 is not applicable. Limited windows are provided inside production facility wherever provided were found protected against breakage by film. All non-production glass including bulbs and strip lights are protected. Sufficient lighting is provided for safe working environment, Suitable and sufficient ventilation is provided. **One minor NC 6 has been raised against 4.2.1; Wall corners behind the resin feeding area of 7 layer B was not maintained in good condition.**
4.3	Utilities
	All utilities within the production and storage areas are suitably designed, constructed & maintained regularly monitored to minimize product contamination. Few of the utilities are cooled air for electronic equipment panels and blown air bubble cooling. Compressed air for blown film generation. These are both generated through compressors drying and filtering air. The processes do not use water in any form directly which can come in contact with product. All water used for hand washing and floor cleaning is through ground bore well and tested for compliance to potability. Process water is tested by Accurate laboratory dated 10th March 2020 Report AL/AHD/10160320040 This is the water used for hand wash process & is potable IS 10500 - 2012 standards.
4.4	Site security and product defence
	All security arrangements are controlled & any movement of persons, visitors or material is monitored through a single point entry gate. Company has provided own 5 persons for 24 hours & these are located at the main entry to the plot & various locations. Site is legally approved with Directorate Industrial Safety and Health Gujarat state Form 4 license to work as factory no 34010 valid till 31 Dec 2022 and Gujarat Pollution Control Board consent no WH

	20771 valid till 17.10.2026. Also available is an action plan approved Swach Bharat Mission. Access is controlled through main gate for the entire premises and again with an entry gate to the unit under scope. Visitor reporting system is in place. There are no external storage of resin or chemicals onsite. All machine room and utilities are adjacent to process areas and connections are controlled by meshes where necessary. Pipes from utilities are adequately designed. The documented Site security risk assessment F/SYS/14 last reviewed on 1st Jan 2020. This risk assessment covers 7 different aspects such as contamination to raw material, packaging material, chemical effect, processing equipment and unauthorised influence, criminal activity, influence of contractors on site. Output of security risk assessment in to a product defence plan PSMS/PRO/06 which covers assessment steps for strategy, outside security, inside security, shipping and receiving security, mail handling, personnel.
4.5	Layout, product flow and segregation
	The factory layout is designed logically to prevent the risk of product contamination and to comply with legislation of factory act. The plan of site is documented as Plant Layout RD/02 Rev 03. Process flow from intake to dispatch is logical. Facility comprises of 3 structures comprising of blowing and gravure section and flexo printing. Site has now extended operations to another new building where pouching activity is now conducted. With the extended area premises are having adequate working space in line with product being handled. All sorting or monitoring checks and activities are conducted on individual production area maintaining same standards of hygiene in an enclosed area. Removal of outer product covering is limited to roll covers of paper rolls on the ground floor warehouse maintained appropriately. Each section has path way to access them. Designated pathways are provided to move. Movement of persons is by singular entrance and exit route. Each of the units have a dedicated entrance and changing facility.
4.6	Equipment
	Necessary Industrial grade equipment such as 3 blown film lines of Windsor 2 of 7 layer and 1 of 5 layer, 2 printing machines (CI Flexo Hutaco & gravure Fadia, 5 pouching machines (XL, Primo pack, Startechno) and all necessary industrial grade machines are provided to manufacture products for the intended purpose and are maintained and used so as to minimize the risk to product safety. All equipment are purchased from tested companies providing industrial grade material and are well maintained. Currently there are no new equipment under installation. Use of wood is minimized inside the production area. All notices are pasted.
4.7	Maintenance
	An effective program for maintenance is implemented by a team of 4 personnel who manage equipment or breakdown to avoid potential contaminations. Company has maintained all the equipment under the scope such as blowing lines(3), printing lines (2), slitting machines (4) and pouching lines (4), courier bag machine (5), FFS pouch machine, Bubble machine, Air compressors

	(4). A monthly preventive maintenance plan is followed for each important equipment. A preventive checklist cum plan is documented to activities to be covered each month. List is maintained in the form of Master list of equipment F/Maint/01 having 24 total units. Company has a team of 3 internal personnel to provide necessary service & contracted machinery suppliers to provide necessary service support. All the equipment is covered under a preventive maintenance program to be maintained once in a month. For each equipment a checklist cum record is maintained, for 5-layer Extruder 16 Different check points maintained covered each month. Seen in this case on 17th Jan / 10th Feb, 20th August / 16th Sept. Printing machine is also attended and recorded on CI Flexo checklist cum record for each month 5 checks done on 19th Jan / 9th Feb, 24th August / 22nd Sept followed by hygiene clearance. All break downs are recorded online in the software developed to monitor them called as Break Down report which is maintained online between 1st Oct to 2nd Nov there are totally 16 recorded break downs such as 2nd Oct 20 on CI Flexo at 10.00 am for centering measurement, 7 layer machine on 5th Oct at 9.00 am. This followed by recording and acknowledgement of hygiene clearance and name of operator who cleared it e.g. R.P cleared breakdown activity on the 2nd Oct 2020. Tools and other equipment is cleared away and appropriately stored. Mostly there are no temporary repairs seen on the site. Engineering workshops are well maintained and do not open directly into production areas kept separately in the next building. All Contractors involved in maintenance or repair is accompanied by a maintenance or staff member.
4.8	Housekeeping and cleaning
	Housekeeping and cleaning systems are in place which ensures that appropriate standards of hygiene through a team of 9 persons of whom 7 persons for inside production area and 2 for external areas. The unit undertakes hygiene and cleaning activities. Entire facility is under compliance to the standard & good standards of hygiene are maintained. Clean as you go policy is maintained. Company have documented a Cleaning schedule this incorporates 12 different areas with their locations, frequency, equipment used, cleaning agents, type of chemicals, dilution rates. Records in terms of Cleaning records Daily F/HR/14 is maintained could verify for each month for each day. Also maintained are cleaning records monthly F/HR/18 covering 16 sections. Company uses 1 mopping machines and many hand-held wipers which are used. The mopping machines are using chemicals such as sterishine by Haylide for floor mopping. Multipurpose cleaner and hand sanitiser in other areas. Toilet cleaning material is stored in a fixed cabinet near the toilet entrance there is one dedicated person identified to clean it. Site has conducted testing of various surface and recorded the findings through an external test report such as following. Compressed air test report AL/AHD/10160320056, Floor swab test report AL/AHD/10160320044 for extruder plant 1, CI Flexo 45, Pouching department 46, change room plant 1 - 47, change room flexo - 48, change room plant 3 - 49. Procedure for chemical and biological control SOP/11 has been documented. Although testing is conducted and sampling points identified the microbiological program has not been clearly documented. **One minor NC 7 has been raised against 4.8.5; The microbiological environmental monitoring being carried out does not define the sampling protocol, frequency of tests, test methods of the identified sample locations.**

4.9	Product contamination control
4.9.1	Glass, brittle plastics, ceramics and similar materials control
	Site has taken steps to avoid and minimize the risk of foreign body or physical contamination. This is done by managing or minimising exposure of glass or brittle plastic to material and process and identifying hazards through a risk assessment and implementation of control. Maximum control is around pre-requisite programs. There is no unnecessary non-production glass or brittle plastic found in the facility during the audit which may pose a risk of contamination. A list of glass and brittle plastic articles RD/23 Identifies all the glass in 6 broad areas and 371 total glasses. A Glass policy is documented in the form of Glass & brittle plastic policy GSFS/M/01/Annexure C. All the necessary actions to be taken in case of a glass breakage are documented in the policy. A monthly - glass & brittle plastic condition monitoring record F-Maint-06 identifies 6 broad areas with condition checked last checked on 19th Oct & before that on 21st Sept conducted on monthly basis for overall condition. All personnel are aware that in the event any breakage occurs a responsible person in charge needs to be informed for necessary actions to be taken.
4.9.2	Sharps and metal control
	Company has documented a Metal & Sharp policy Annex 06 for management of sharp instruments. These are either hand held cutters or slitting blades installed on machines such as slitting machine, blown machine or other locations. The blade issuance and collection is department specific such as extrusion blowing and slitting only and there is an online record system incorporated in the software. An online report is generated in the software as seen in case of machine blades which are used for slitting or cutting operations in the month of oct between 1st to 15 Oct totally 381 blades were issued on 74 different issuances. For hand held cutters these are issued to individual persons once in a month given and taken back last such activity was in 1st Oct where 44 blades were issued and old blades collected. Company policy prohibits the use of snap off blade Clause 4.9.2.4 is not applicable.
4.9.3	Chemical and biological control
	The manufacturing process involves blown film extrusion, printing by using ingredients such as PE & PE based resin followed by printing of these films. A List of approved chemicals RD/12 covers possible chemicals being used such as cleaning chemicals, grease, compressor oil, gear box oil lubricants and so on. All material being use is developed as per process requirements and under gone a risk analysis process. Risk assessment is conducted for control and management of chemicals or any possible allergens as a part of as a part of Hazard Analysis of HACCP manual. Company routinely conducts product contact migration test to check possible impact on material on random basis. Refer to report MUM/001770/2020 dated 14/9/2020 for Overall migration test EU 10 / 2011 on milk packaging and ghee packing LFDE film.
4.10	Waste and waste disposal

	All wastes are trims of multi-layered. All plastic waste undergoes egglomeration & shredding conducted company themselves. The site has installed an egglomerator and extruder themselves where both unprinted and printed films are converted into individual types of resins. The unprinted resin are used back by the company in to ecommerce packaging. The printed resin are sold to users who may make pipes and other applications. The site makes almost 1500 kgs of such resin per day. For slit trims bins are provided for temporary storage however in process solid waste is minimal and does not constitute significant amounts. All waste is disposed after segregation in to solid plastic and liquid chemical residue. There is no third-party destruction or transfer of waste to be undertaken clause 4.10.5 is not applicable.
4.11	Pest management
	This site is of adequate area measuring 4900 square meters and maintained to appropriate standards and comprising of a ground plus single storey structure. All external opening are well managed with adequate closures. The site has developed a preventive pest control program by using services of external service provider along with minimal external openings and monitoring of pest catching devices. The pest control program provides devices such as electric fly catchers for flying insects, rodent glue pads and spraying of external premises as a prevention of harbourage. A contract is made with PCI of India contract no 0536 from 1st July 2020. The contract indicates 6 services taken for Rodents, Spider, crawling pest, lizard, fly management for each service is ranging from monthly, weekly, fortnightly. The pest control operator monitors rodent boxes & electric fly catchers. Spraying is done externally for the target pests. Site does not undertake own pest control but monitors the catches in bait stations or electric fly catchers. The handling & application of chemicals is external and managed by the contracted service provider. Clause 4.11.3 is not applicable. Pest control equipment such as bait stations & electric fly-killing devices are appropriately located and operational during the audit. Adequate number of electric fly catchers is provided. An updated location map for 51 rodent boxes inside and outsides can be seen. There are 14 electric fly catchers on site found appropriately located and functional. There have been no changes in the lay out and number of devices as yet. For each service undertaken a pesticide usage log is provided by service provider in the form of service log card – service visits for IFM were conducted 8 times between 3rd July to 20th Oct. Visits for integrated lizard management were done 4 times between 3rd July to 1st Oct. Visits for Rodent were Rodent 8 times between 3rd July to 20th October. A detailed MSDS file is maintained for the chemicals being used on site. Employees understand signs of infestation. If there is any occurrence which requires elimination of hazard then appropriate actions are taken to evaluate the potential damage. A catch analysis is maintained and graphically presented seen in case of lizard, rodent and fly catcher. Refer to fly catcher analysis / Lizard and Rodent analysis from Dec-19 to Oct 20.
Non-applicable clauses	4.2.3, 4.9.2.3, 4.10.6, 4.11.2

5.	Product and process control
5.1	Product development
	Site specialises in multilayer coextruded film manufacturing which can be an alternative to laminates. All products are developed as per customer requirement through an industry acceptable standard procedure of sharing and updating end product specification based on application. Majority of products are multi-layered plastic film which are developed by company for oil and milk applications and offered to customers. Site has specialised operations for ecommerce industry which is packaging for online material sales for reputed ecommerce brands. Company develops own recipes as a means of trial manufacture which can be offered to customers. All products have a specific purpose and developed to meet customer requirements. All requirements from customers are taken in consideration to produce packaging suitable & developed for its intended use. Purchase confirmations & orders are received from customers specific product requirements are stated in it. In majority of cases company offers own developed products. The requirements are converted in to job order for execution based on quantity to be produced at that time. The details of job order include all the information including type and grade of raw material, dimensions, physical & functional parameters as well as mediums and production information as well as specific quantity to be produced. There is no use of recycled material. Production trial is carried out first if specification is developed by the company exclusively for the customer. Most trials are standardized for products & application types. Typical production trial method involves developing of product substrate based on sample provided by customer. Production trials are a continuous process and now company has developed 106 plus combination of product specifications. These are also called as recipes. The combination are used to be further printed and then converted in to pouches or bags. Company ensures that production is carried out using defined operating conditions that are tried and tested for various individual operations of printing lamination & other procedures. A technical specification sheet covers the process and substrate requirements. This could be developed on the basis of suggested application from the customer. Maximum number of times the site develops a technical specification for a customer and then it undergoes trial at the customers end. A technical specification sheet was developed for Bubble bag application this had an internal spec code 7R54. The film specifications considered GSM, hot tac, COFS, COFK, Treatment Dynes, dart impact, opacity, elongation, TD/ MD, Tensile strength TD/MD. In case of pouches some more specifications consider roll width, film type, width, flap size, gusset type, strip item. The data is converted into a job order. Transfer of customer specifications in to company's information is part of the software program where the specs are available in the form of job order given on the machines in printable form. In case of B/W Film NP5 Polybag 270 x 180 + 50 was produced against job order POJ/875 covering all the requirements. This information is automatically picked from the software program. The authority of filling in customer specs which will be used to make job order is with 3 identified company personnel.
5.2	Graphic design and artwork control

	Artwork and all pre-press processes conducted by the site is managed to ensure loss of information the printing involves use of flexo and gravure printing. Controls are evident and demonstrated by following an art work check and proof sharing system. Company has documented a procedure for artwork approval PRO/QC/03 for management of art work this captures all the steps of the requirement from collation of information to receipt of art work to verification & approval by customer. A process to seek formal acceptance is followed in place by sending a trial art work proof file to customer and exchanging information through the stake holders. Each time art work is needed to be converted in to gravure cylinder or flexo plate an approval is taken from customer. In case of Quality Kosher Poultry mail was sent on 29 August approved on the same day. There is a service provider who develops art work. Can verify a customer approved proof maintained on site for Sagar Ghee 1 litre approved customer on 27th August 2020. Where this is not possible an internal quality approved print LSD is maintained as seen in case of Maruti Dailry Tej Special milk 500 ml NPF/LSD/729. Print trials are carried out during execution of each sales order for each product specification. This is recorded directly online in the system as seen for job order PJ 240 being printed on 14th May seen during the audit. A customer approved copy as well as QC approved is made available for reference to be compared against each standard. Printing cylinders & plates are traceable to product name and bear a specific number traceable to the product type. Can verify gravure cylinders & flexo plates being maintained in a cabinet in QC lab. A file docket with customer approved art work is maintained for each product specification maintained with quality team. Company has a service provider where management of artwork and subsequent creation of print plates through another service provider is conducted. Company identifies a physical location where in all shade cards & plates are kept which are obsolete are isolated from library the procedure mentions the manner of control on obsolete art work and plates.
5.3	Packaging print control
	There are 2 types of printing activity gravure and flexo and depending on the complexity of the jobs this is chosen. All information pertaining printing is managed to ensure clarity of shades, design, colour and applicable aspects. During printing checks are undertaken to ensure printing is compared to customers approved material. All printing is verified against suitable Pantone shades and correctness of text matter. An online printing book is maintained where each print trial is verified. Print blankets have a designated room where they are stored. All print runs are checked against customer or quality approved sample which is generated by Quality department for correctness. During the audit a consolidated summary of production details of a printed job along with approval and reference card is maintained on site. Can verify a customer approved proof maintained on site for Sagar Ghee 1 litre approved customer on 27th August 2020. Where this is not possible an internal quality approved print LSD is maintained as seen in case of Maruti Dailry Tej Special milk 500 ml NPF/LSD/729. Printing errors are checked for type of prints or colour shades & Text matter misprint if any. Site has made all data online with each job being checked and recorded in a computerized data entry through a specially developed software. During printing both hard copy record of printing data quality control sheet and soft data is maintained. Could be seen maintained for job Tej Special milk 500 ml covering aspects such as treatment, shade, text, coil width, photo cell width, winding direction.

	Removal of previous job printing material are identified CCP and checks are carried out instantly and recorded online in the software during the execution. There is no composite prints undertaken on site clause 5.3.5 is not applicable. Samples are at least retained for 1 year since executing of order. All unused material is disposed internally destroying the same. There is light table provided for monitoring of flexo and gravure printing.
5.4	Process control
	Quality monitoring at relevant locations is undertaken and followed at each process step. Procedures are in place to ensure effective quality assurance of operations is maintained at all times by a team of 5 personnel referred as Quality Assurance department distributed in various departments. Steps which are critical to the product safety and quality are identified and control, monitoring and recording system is established. Company has identified process control points which are critical. HACCP plan defined and risk assessment is carried out. For each hazard that requires control, control points are reviewed to identify those that are critical. There is a logical approach by using decision tree in identifying CCP's as 02 CCP's are identified. CCP 01 is at Blown Film process which is Corona treatment as per required range dyne level of minimum 38 for work order EX/1319 which was run on 2 Nov at night time and ERP data mentions the average dyne value for each roll 205L003348 where the value found to be 40 recorded in Extrusion receipt. This is recorded in ERP system online for each roll. For CCP 02 and its monitoring the site maintained in ERP system during unloading of each roll. In case of job order no PJ/1249 for roll no 205L003351 printed was cleared of previous job PJ/1243 as well as 7 different aspects (balance rolls / ink / master shade card / cylinder plates /film types / job change waste / designated place assigned) are checked. colour shade and text matter. Equipment used in all processes are developed for manufacturing processes of Blown film extrusion (5 /7 Layer process log sheet F/EXT/02) , Printing (Printing job order & log book F/PMT/01), Pouching (Pouch production report) will ensure the monitoring of each process control points. Site has updated their systems of process monitoring and recorded them online on a customised software. This is tracked at each process step. Bill of materials are part of job order. This contains information such as all those material and inputs which go in to making the final product as well as details of composition of each layer as in case of extrusion. Depending on the purpose of the film or pouch a job order is created for particular product type. Inputs of product type are standardised in the form of a recipe which is unique to its application and used during creation of the base film in extrusion. Depending on printing or pouching if to be undertaken this converted in to pouch job order (PJ/1249, PJ1243, PJ1244) or printing job order or slitting job order. All links are generated by the system and accordingly all processes are undertaken. First process will be extrusion of the film then followed by printing if applicable, slitting and pouching if applicable. All data is now immediately entered online. Documented checks of production are maintained continuously where applicable and recorded in respective processes of extrusion, printing, pouching as an example. The process is now developed online.

	Extrusion process step (online record Extrusion receipt) covers checks undertaken onsite which are width, thickness treatment seen incase of sale order no SO231 which extruder order EX/439 then sample is taken to lab for off-site checking such as hot tac , inner cof static / kinetic, outer cof static / kinetic, dyne value, dart impact, Opacity, elongation and tensile TD/MD this is entered in Ext receipt on 22 June 20. In the next process step printing quality checks are undertaken sale order no SO231 is now identified as print PJ/412 for colour shade and text matter and also entered online on Printing receipt (PJ/1412 on 23 June on roll no 20GRA000407/408/406. Slitting activity is also recorded for this sales order as SLJ/615 was checked for size coil width, shade. Next step pouching done on 29 June 20 and quality checks were width and length and sealing. Finally, a certificate of analysis is generated as seen in this case of PLP/446 OPA Vacuum pouch film nat. At each process step a line clearance is maintained. This is now an online process in the ERP. Area line clearance was seen maintained in EX 1319 conducted on 1 Nov & previous job was EX1318 and 4 checks were conducted. In printing this was done between PJ1248 and PJ1249 on 1st Nov 7 checks were undertaken. Line clearance is documented as a SOP but ERP based controls are required to be maintained.
5.5	Calibration and control of measuring and monitoring devices
	Site conducts processes of blown film extrusion, printing, slitting, pouching using dedicated equipment running at various speeds. The equipment are calibrated and site it able to demonstrate that measuring and monitoring equipment as assigned on process equipment is sufficiently accurate and reliable to provide results. There are monitoring devices on temperature, speed & weighment devices for final packing. All quality-based measuring equipment are calibrated annually. A Master list of equipment such as Master-list of calibration instruments F/QC/02 IS identifying 24 measuring equipment in quality lab. Few instruments in process such as extrusion machines have inbuilt error and correction mechanism. Calibration of master is undertaken by NABL approved laboratories. Results of observation are available along with the certificates are maintained. Temperature controller Sr no NM/NPF/HTT/TI/02 located on hot tech equipment was calibrated against cert no ALL/E/010320/002 dated 1.3.2020, Dart impact tested located on in Dart machine tested DSH/13-14/030/080 on 2.1.20 cert DSH/CAL/19-20/467, weighing scale 200 Gm calibrated through Accent instruments cert AI/20-21/199. All standard weights are also calibrated through an authorized agency Accent Instruments. Other labs such as Accurate lab LL are used. All the labs use masters used have calibration which is traceable to national standards (NABL). Universal calibrator 116033787 was traceable to certificate no Calibration cert no C19110450/E/01-A-01. Necessary corrective actions are identified if any in parameter is not confirming related to process material in manufacturing, quality inspection or other locations is found if equipment failure occurs. Any such occurrence is investigated and immediate actions are taken to ensure no repeat occurs.
5.6	Product inspection, testing and measuring
	Inspection procedures are documented as Test Procedure manual quality control QC/SOP/01 this also contains reference to Quality assurance plan RD/09 which is being implemented by a team of 6 personnel who carry our simple physical testing.

	Quality checks are carried out in individual sections & steps of extrusion, printing, slitting, pouching. Routine off-line quality checks are carried out at practical points which are during and at end of each process. Quality checks are carried out for each roll in each process. Extrusion (13 tests – width / thickness / GSM / COEF Static/ COEF Kinetic / hot tack / dart impact / tensile MD & TD / Elongation MD & TD / Opacity / surface treatment). Printing (shade and test matter), Slitting (width mm), Pouching (leak test / width / length / adhesion). The testing equipment being used are calibrated annually to verify their accuracy and also monitored through product reliability testing. As a result of direct process monitoring and quality checks a certificate of analysis (COA) is generated covering various parameters such as width, opacity, thickness, GSM, Coef inner / outer static and kinetic, surface treatment, dart impact, hot tack, tensile strength MD / TD , Elongation MD / TD, Print defects and so on. Could verify a COA for product Shrink Film NAT against packing list PL/1783. This covered adherence to various parameters as identified in the quality plan. Company has conducted internal reliability tests done for film parameters such as width, thickness surface treatment, opacity, GSM, COF (inner & outer kinetic) , tensile MD/TD, elongation md/td and dart impact conducted by the company internally and with a customer (Shako Flexi pack). Refer Test reliability record F/QC/08 conducted for roll no 207LB001378 for width / micron / surface treatment / opacity / GSM / COF inner conducted on 5th August with one external company and 4 inspectors. Company uses external testing NABL approved laboratories which are meeting ISO 17025 requirements. But there is no requirement for inline testing as all activities are done manually as in case of transferring to each stitching line. Clause 5.6.2 is not applicable. Since inline inspection is not applicable there is no need to specify accuracy of such equipment. Clause 5.6.3 is not applicable. There is no system of diverting any nonconforming product clause 5.6.6 is not applicable. There is no automated vision system in place which may be required to check product conformance or accuracy besides printing. Clause 5.6.9 is not applicable.
5.7	Control of non-conforming product
	All manufacturing is specific to product required by customers. Site can ensure that any out-of-specification product is clearly identified and controlled appropriately. Company has documented a Procedure for Control of Non-confirming Products SYS/PRO/04 which identifies types of non-conformances in raw material, in process and final product. All products are assessed for their adequacy on the immediate basis. Suitability can be derived through testing, visually checked & assessed for decisions are made as applicable by the Directors. Actions are implemented to ensure there is no repeat of non-confirming products is taken. There has been very few occurrences where finished product was found to be non-conforming.
5.8	Incoming goods
	All incoming goods are raw material such as PE, PA, EVOH, Master batch which are resins, 2 types of inks (gravure / flexo), oils & packing material, pallet, engineering. Facility converts all consumables into finished products on site and accepts material against incoming inspection. All incoming lots of resin or inks are assigned a lot number based on supplier's identification and

	assigned a lot number. Resin of grade 310E of batch R014K8708J and Bangram 4108 grade of lor no 20060130 could be seen. The necessary information and MSDS of this material could be traced. Procedure for store PRO/STR/01 is documented to explain the requirement. Company has assigned a system of tracking all inputs based on use on specific job orders. All lot numbers and grades being used are tracked based on it. Each resin grade is product specific and lot numbers are tracked for inputs. All incoming material lots are received and documents are checked for certificate of analysis or declaration and also vehicle-based checks are undertaken. This is recorded on incoming material register F/STR/01 checked for each lot received on 21 Oct for material 1018MK invoice no 619 lot no 71918E2A21 checked for odour, oil spot, packing condition, vehicle cover.
5.9	Storage of all materials and intermediate and finished products
	Site manufactures resin in to films and prints them to be converted in to pouches or bags. Procedure for storage provides guidance for these activities. There are dedicates storage areas for resin and during process of conversion each job is suitably stored in that area. A sales order SO 231 could be traced through individual process steps such as Extrusion p extruder order EX/439. In the next process step printing sale order no SO231 is now identified as print PJ/412. Slitting activity is also recorded for this sales order as SLJ/615. Next step pouching done on 29 June 20 and quality checks were width and length and sealing. Finally, a certificate of analysis is generated as seen in this case of PLP/446 OPA Vacuum pouch film nat. Site has moved to an online data capture system where in all the orders to be executed in the process are available on the site and data pertaining to input and output is entered immediately online.
5.10	Dispatch and transport
	The receipt of raw material and dispatch of finished goods is undertaken in closed ware house and operational controls are maintained to ensure safety of materials handled. Incoming checks and outgoing checks are evident. All raw materials are resins which are mostly PE based, PA, EVOH resin converted in to multi-layered film. Resins are verified for receipt and finished goods are checked for final packing during dispatch. Company may use pallets in case of export consignments. There are 3 company owned vehicles used for delivery on site these are used and maintained between group company Navrang polyfilms and this site. The cleaning of own vehicle is recorded on the 1st Nov GJ18 AZ 4749 was cleaned and recorded for odour, floor check and cover condition and material condition. Most vehicles used for procurement and delivery are contracted and are subject to recorded checks. Recorded checks for dispatch are recorded in Outgoing vehicle inspection record F/DISP/02 this register maintains track of non-export consignments e.g. on 13 May dispatch was made to Saraswati foods through GJ18AZ checked for smell, oil spots, cover of vehicle, condition of packing, floor condition is verified. For export all shipping containers are used Container stuffing & vehicle inspection report F/DISP/03 as can be seen in case of invoice 942/20121 loaded on 20 Oct in container TCNU 4108745-40 inspected for 7 check points.

	All consignments exported through use of non-reefer container cargo. Local transport is through contracted agencies such as Khodiyar roadways, Krishang cargo and so on.All Vehicle drivers entering the premises are made to comply with company site rules as well as site rules.
Non-applicable clauses	5.3.5, 5.6.6, 5.6.9

6.	Personnel
6.1	Training and competence: raw materials handling, preparation, processing, packing and storage areas
	Site employs 150 plus personnel and they are adequately trained, instructed and supervised with their activity and that they are competent to undertake their job role. Top management is involved in standardisation of the equipment and provides direct on the job training. There are 28 key personnel & other workers who undertake manual work. All personnel are trained through a developed training calendar. Ref Annual training calendar F/HR/05. Company has developed an annual training calendar 2020 which is covering 12 topics for all identified personnel. Training topics cover aspects such as BRC awareness, GMP, site security, HACCP principles, Print packaging control, online inspection, CCP monitoring, metal detector operations and other aspects such as TACCP / VACCP. Company has developed and Induction training plan there have been 4 recent new employees this year who have undergone induction training. Can see one case of Jayshri Prajapati who has joined as Extrusion department on 11th October and topics covered were organization overview, functional responsibility, CCP, manufacturing process, GMP, incidents, site security, safety policies. Personnel involved in important aspects such as CCP & quality checks are also found to be trained on 25th Jan / 18th Sept where 3 persons from Quality / Printing were trained on CCP. Product quality related training was done on 26th October attended by 3 persons from production slitting/ pouching / slitting - quality. These are recorded on Training imparted record F/HR/03 subject of training duration and evaluation dates are also recorded. Company has developed competency matrix for 28 specific personnel who influence key activities in important positions. Personnel competence records F/HR/01 are maintained (Slitting QC joined since 24.5.20). This matrix identifies departments. Designation, required and available education, experience and justification of suitability is captured. A training need identification format is used with 12 different types of training topics. Majority of training topics are found to be identified as refresher. Training is in English & local language. Refer to Training need identified F/HR/02 maintained on site. Company has maintained training evaluation system and records it in Training evaluation sheet F/HR/04 this was seen implemented for a case on 18th Sept where CCP training was been provided evaluated in the form of score 0 to 3 where score of 2 is improved working.
6.2	Personal hygiene: raw materials handling, preparation, processing, packing and storage areas
	The site's personal hygiene standards have been developed and implemented to minimise the risk

	of product contamination from personnel. Site monitoring is implemented. Company has established a procedure for Personnel & Plant Hygiene Policy Annex-E which describes the rules to be followed inside the production area. Jewellery and wrist watches are not allowed inside the production area as per policy. All the requirements are also displayed inside the factory. Implementation of jewellery control was not adequate leading to a minor NC as below. Hand wash basins are provided for same purpose & written in policy / Work instructions. Mobile phones are not allowed & lockers are provided for storage of personal items. Based on risk 19 authorised personnel from management or heads of departments are allowed to carry mobile phones. Refer to Mobile authorization inside plant area F/HR/16 is in place which allows 24 senior personnel. Personnel & Plant Hygiene Policy Annex-E restricts the use and storage of personal medicines to minimise the risk of product contamination. Fingernails are found to be kept short. Personal hygiene checks are conducted before entry by security personnel & then on random sampling per month recorded on Personal sanitation and hygiene records are maintained. So far from January till date 6 cases have been reported for minor variation in following GMP and accordingly action has been taken. Personnel with open wound are not allowed to work in production area they are encouraged to report any such incidents to their reporting personnel. Decision to allow plasters will be taken by the management. **One minor NC 8 has been raised against 6.2.1; Jewellery control was not well implemented as few of the personnel were found to be using hand threads.**
6.3	Staff facilities
	Facility has provided sufficient staff facilities in 3 separate entrances such as to blown film, flexo printing and pouching. These are in line with number of personnel working and are designed and operated to minimise the risk of product contamination. These facilities were kept in a good and clean condition. Totally 100 lockers were available distributed for all 3 sections. Lockers are of reasonable size to store all the items. Company-issued protective clothing is provided and personal clothing is stored in same lockers but in different poly bags. Eating and smoking is not allowed in locker and changing rooms. Hand washing facilities with sufficient quantity of water, unscented liquid soap, air dryer is provided to enable cleaning of hands before commencing work. Toilets are located externally of each of these 3 sections. Facilities for visitors and contractors are adequate and enable compliance with the site's hygiene policy. A visitor health status questionnaire F/HRD/12 is required to be filled before the entry. No eating, drinking inside process area is allowed and designated area is provided for consumption and storage of food tiffin. Water dispensers are provided before the entrance to production & certain locations considering the individual departments. Smoking is not allowed inside the facility. Clause 6.3.11 is not applicable.
6.4	Medical screening
	Company undertakes health condition checks of all personnel that may affect product safety which is as per legal requirement and monitored. All visitors are required to fill a Visitor Contractor Health Questionnaire Form F-HRD-12.

	Organization performs medical health check-ups for all personnel at the time of recruitment. This is a planned activity and it is performed on annually or before joining. This monitoring is being done by HR and is also a part of legal requirement. The personnel joining the site undergo own checks and are again tested by the authorities. Can verify physical examination for 150 + personnel is conducted, Ravindra Singh Pouching / Senu Kumar Extrusion, Kapil Yadav Pouching who were checked by Dr Dharmesh Vora. Personnel are encouraged to declare any possible health condition which they may find unsuitable for factory.
6.5	Protective clothing
	All personnel are provided with appropriate protective clothing such as aprons to be worn above existing clothing. Hazard and risk principles are used to determine the need to wear such clothing and company has provided 2 sets of T Shirts which is worn from home and at the site they wear an apron is required to be worn. Site has established Policy for protective clothing POL-08. Most office staff is travelling to the facility through or own vehicles. Maximum shop floor personnel are provided with staying facility near the production area in a dormitory and travel on their own. Laundering is conducted through a contracted service provider Vishal Thakore who collects and brings back them after laundering and a laundry register is maintained where the collection and return after washing is recorded. Lack of contracted arrangement lead to a minor NC as below. All personnel wear own shoes and shoe covers are worn only before entering production area. Head hair nets are provided to all as required snoods or beards. **One minor NC 9 has been raised against 6.5.7; Details of the contracted laundry service provider was not available on site.**
Non-applicable clauses	