

REMOTE AUDIT

GARIS PANDUAN PELAKSANAAN AUDIT SECARA TIDAK BERSEMUKA DI LOKASI FIZIKAL BERBEZA (*REMOTE AUDIT*)

**(Pindaan 1)
Berkuatkuasa mulai 1 Oktober 2021**



**KEMENTERIAN KESIHATAN MALAYSIA
BAHAGIAN KESELAMATAN DAN KUALITI MAKANAN**



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GARIS PANDUAN PELAKSANAAN AUDIT SECARA TIDAK BERSEMUKA DI LOKASI FIZIKAL BERBEZA (*REMOTE AUDIT*)

1. PENGENALAN

Penularan wabak penyakit COVID-19 dan pelaksanaan Perintah Kawalan Pergerakan (PKP) telah menghadkan pergerakan dan perhubungan orang ramai secara bersemuka. Ini memberi impak kepada aktiviti audit yang dilaksanakan secara bersemuka.

Perkembangan Teknologi Maklumat dan Komunikasi (ICT) membolehkan aktiviti audit diteruskan dengan melaksanakan audit secara tidak bersemuka di lokasi fizikal yang berbeza atau *remote audit*. Pelaksanaan audit secara *remote* ini adalah sama dengan audit secara bersemuka tetapi menggunakan kemudahan teknologi maklumat (IT) bagi mendapatkan penemuan audit dan menilai secara objektif tahap kepatuhan pihak industri terhadap keperluan audit tersebut .

Garis panduan ini disediakan sebagai panduan kepada juruaudit KKM dalam melaksanakan audit secara tidak bersemuka di lokasi fizikal berbeza (*remote audit*).

2. OBJEKTIF

Memberi penjelasan mengenai skop, keperluan dan prosedur bagi pelaksanaan audit secara tidak bersemuka di lokasi fizikal berbeza (*remote audit*).

3. DEFINISI

Audit secara tidak bersemuka di lokasi fizikal berbeza (*remote audit*) adalah audit yang dilaksanakan secara maya dengan menggunakan kemudahan teknologi maklumat (ICT).

4. SKOP

Audit secara *remote* adalah merangkumi semua proses audit iaitu perancangan, penetapan, pelaksanaan dan penyediaan laporan audit bagi aktiviti pensijilan, pengiktirafan, pelesenan dan penyenggaraan premis makanan di bawah Program Keselamatan dan Kualiti Makanan (PKKM).



5. SYARAT DAN KEPERLUAN AUDIT SECARA *REMOTE*

- 5.1. Audit secara *remote* terpakai hanya bagi audit yang berikut:
 - a) Audit bagi tujuan surveilan/pengawasan
 - b) Audit susulan (*follow-up*) bagi tujuan verifikasi penutupan ketidakpatuhan (non-conformance)
 - c) Audit bagi tujuan pembaharuan sijil secara bersyarat:
 - Premis mempunyai sejarah pemantauan pelaksanaan audit yang memuaskan
 - Premis mengeluarkan produk makanan yang berisiko rendah; dan
 - Tiada perubahan operasi atau bahan mentah sedia ada.
- 5.2. Audit secara *remote* tidak terpakai bagi audit pematuhan (*compliance*), penambahan produk (*added produk*) dan pembaharuan sijil yang tidak mematuhi syarat 5.1.(c).
- 5.3. Audit secara *remote* hanya boleh dilaksanakan dalam tempoh pandemik Covid-19 atau keadaan lain yang ditentukan oleh PKKM.
- 5.4. Penilaian perlu dibuat mengenai kemudahan dan kemampuan mengendalikan peralatan ICT sebelum membuat keputusan untuk melaksanakan audit secara *remote*.
- 5.5. Pihak premis perlu menyediakan kemudahan peralatan ICT, kamera video dan talian internet yang stabil dan tenaga kerja untuk mengendalikan rangkaian mesyuarat / audit secara maya, memuatnaik dokumen serta rekod dalam sistem atau aplikasi seperti Google Drive dan mampu mengendalikan masalah berkaitan rangkaian.
- 5.6. Pihak auditee bersetuju untuk audit dijalankan secara *remote* dan memberi kebenaran kebolehcapaian "*accessability*" dokumen, rekod dan data yang disimpan dalam sistem atau aplikasi seperti Google Drive kepada Pasukan Juruaudit.
- 5.7. Rakaman kamera video bagi sebahagian atau keseluruhan audit ini boleh dilakukan atas persetujuan kedua-dua pihak.



6. PROSEDUR MENJALANKAN AUDIT SECARA *REMOTE*

6.1. Persediaan awal yang perlu dilakukan oleh Pasukan Audit sebelum melaksanakan audit secara *remote*:

- a) Mengadakan perbincangan ketua juruaudit dengan juruaudit mengenai pendekatan dan media interaksi yang akan digunakan dan aliran audit (*audit flow*);
- b) Menetapkan tarikh audit, menyediakan agenda audit dan maklumkan kepada pihak auditee melalui email dan diikuti dengan surat rasmi;
- c) Tempoh atau bilangan hari (*man-days*) yang diperlukan bagi melaksanakan audit akan ditentukan oleh ketua juruaudit dengan persetujuan pihak auditee;
- d) Mencuba uji (*trial run*) sistem media interaksi yang akan digunakan sekurang-kurangnya 5 hari sebelum tarikh audit sebenar dijalankan.

6.2. Prosedur bagi menjalankan audit secara *remote* adalah sama seperti prosedur audit sedia ada secara bersemuka. Pendekatan audit secara *remote* boleh dilaksanakan seperti berikut:

- a) Mesyuarat Pembukaan (*opening meeting*) boleh diadakan secara *video conference with screen share* atau *real-time video images* menggunakan aplikasi seperti Google Meets, Zoom atau Microsoft Teams.
- b) Senarai kehadiran (*attendance list*) boleh dikemukakan oleh ketua juruaudit secara email kepada pihak auditee sebelum mesyuarat pembukaan dan meminta pihak auditee menandatangani dan kembalikan semula kepada ketua juruaudit dalam bentuk imbas (*scan*) pdf atau ketua juruaudit membuat rakaman skrin sidang video (*screen shoot of video conference*) sebagai bukti kehadiran.
- c) Lawatan Lapangan (*on-site visit*) secara maya bagi keadaan infrastruktur premis, operasi pemprosesan, kemudahan sanitasi, pengstoran dan sebagainya boleh dilakukan menggunakan *video conference with screen share*, *real-time video images obtained with drones*, tablet atau telefon mudah alih (*mobile*) atau kamera video tetap (*fixed video cameras*) dan membuat rakaman skrin (*screen shoot*) bagi mengumpul penemuan audit (*audit findings*).
- d) Pasukan audit perlu menyenaraikan dokumen dan rekod yang akan diperiksa dan memaklumkan terlebih dahulu kepada pihak auditee sekurang-kurangnya seminggu sebelum tarikh audit.



- e) Pihak auditee perlu memuat naik (*upload*) dokumen serta rekod dalam aplikasi seperti Google Drive dan memberi kebenaran kebolehcapaian “*accessability*” dokumen, rekod dan data yang disimpan ini bagi tempoh masa tertentu kepada Pasukan Juruaudit. Pasukan Juruaudit boleh membuat rakaman skrin (*screen shoot*) dokumen dan rekod ini sebagai penemuan audit (*audit findings*).
- f) Temuduga auditee dan perbincangan antara pasukan juruaudit boleh dilakukan melalui *video conference* dengan menggunakan applikasi seperti Google Meets, Zoom atau Microsoft Teams.
- g) Senarai semak dan borang *Corrective Action Request* (CAR) sedia ada perlu digunakan untuk mencatatkan penemuan audit dan ketidakpatuhan (*non-conformance*). Juruaudit boleh merujuk kepada **Lampiran 1-** Panduan Menjalankan Audit Lapangan Secara Remote dan **Lampiran 2-** Panduan Menjalankan Audit Dokumentasi Secara Remote yang disertakan sebagai rujukan semasa menjalankan audit *remote*.
- h) Mesyuarat penutup (*closing meeting*) boleh diadakan secara *video conference with screen share* atau *real-time video images* menggunakan applikasi seperti Google Meets, Zoom atau Microsoft Teams.
- i) Ketua Juruaudit hendaklah memaklumkan kepada pihak auditee penemuan audit berdasarkan kepada borang CAR yang telah dipersetujui oleh pasukan juruaudit. *Screen share* borang CAR boleh dilakukan (jika perlu) berdasarkan permintaan pihak auditee semasa mesyuarat penutup.
- j) Setelah penerimaan (*acceptance*) penemuan audit oleh pihak auditee, ketua Juruaudit sahaja yang perlu menandatangani borang CAR tersebut, imbas dalam bentuk pdf dan email kepada pihak auditee untuk ditandatangani dan dikembalikan semula kepada Ketua Juruaudit dalam tempoh masa satu (1) hari selepas mesyuarat penutup audit dijalankan.
- k) Laporan audit hendaklah dihantar ke PKKM dalam tempoh masa yang ditetapkan dalam prosedur audit sedia ada.

7 RUJUKAN

- i. Standard ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management system.
- ii. IAF MD 4: 2008, IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing /Assessment Purposes.
- iii. ISO & IAF 2020, ISO 9001 Auditing Practices Group Guidance on: Remote Audits.



PANDUAN MENJALANKAN AUDIT LAPANGAN SECARA REMOTE

		FOOD SAFETY AND QUALITY DIVISION MINISTRY OF HEALTH MALAYSIA	FORM 1-REMOTE
GUIDELINE TO CONDUCT SITE AUDIT REMOTELY			
conforming premise name and address:			
Request factory representative to bring the camera near entrance to show the factory name and address (if provided) on its signboard)			
Factory Name:			
Date of Remote Audit:			
1. Prevention of COVID-19 SOP			Tick (/) if completed
1.1	Body temperature Scanning Device and its position: Request factory representative to bring camera to show thermometer is place at the main entrance of the factory.		
1.2	Screening of worker body temperature and MySejahtera Registration: Request factory representative to bring camera to show workers are screen for temperature, wearing face mask and scanning of MySejahtera or recording into registration book at the main entrance to the factory. 1.2.1 Individual Entre by Walking: Request factory representative to bring camera to show the movement control of the visitors and workers at the main entrance (e.g. gate always close and not allowing workers/outside go into the premise without screening). 1.2.2 Individual Entre by Vehicle: Request factory representative to explain and demonstrate the procedure for vehicle to enter factory (e.g. body temperature screening of all the personnel in the vehicle, scanning of MySejahtera and hand sanitization & wearing face mask after getting out from vehicle).		
1.3	Hand Sanitizer: Request factory representative to bring camera to show hand sanitizer is place at the main entrance to the factory.		
1.4	Health Declaration: Request factory representative to bring camera to guard house to show evidence that visitor is required to declare health status before entering factory area.		
1.5	Social Distancing: Is social distancing effectively practiced when worker entering factory, screening temperature and other related area. 1.5.1 Canteen/Pantry/Rest Room Request factory representative to bring camera to show canteen/pantry to verify following: a. Is there any marking in the canteen/pantry for social distancing? b. Is there any hand sanitizer provided? c. Is there notice stating maximum people allow to be at one time?		
	1.5.2 Praying Room/Surau Request factory representative to bring camera to show surau/prayer room to verify following: a. Is the praying mat/ tool sharing by workers? b. Is there any hand sanitizer provided? c. Is there notice stating maximum people allow to be at one time?		



1. Prevention of COVID-19 SOP (continue)		Tick (/) if completed
1.6	<p>Covid19 Control Poster/ Notice Request factory representative to bring camera to verify following: Is there any poster or notice regarding prevention of COVID-19 in the premise?</p> <p>Is there any notice stating maximum number of visitors at one time?</p>	
2. Factory Surrounding Area		
2.1	<p>Factory location* and condition of surrounding area: Request factory representative to bring camera around factory within its perimeter area to show: (*Note: Auditor may use google map application and by using satellite view to identify any source of contamination such as sewerage treatment plant or waste dumping ground within 500-meter radius from factory site prior to the audit to determine source of contamination.</p> <p>2.1.1. Is the factory perimeter area adequately fenced?</p> <p>2.1.2. Is there any source of contamination?</p> <p>2.1.3. Is there any overgrown vegetation or trees?</p> <p>2.1.4. Is there any placement of unused machine or rubble?</p> <p>2.1.5. Is the ground paved and properly drained?</p> <p>2.1.6. What is the condition of drainage surrounding building?</p> <p>2.1.7. Is there any sign for pest infestation?</p> <p>2.1.8. Is there any food handling activity taking place in open area?</p> <p>2.1.9. Any other non-conformance (if any)</p>	
3. Changing Area, Hand Washing Facilities and Toilet		Tick (/) if completed
3.1	<p>3.1.1. Entry to Processing /Changing Area: 3.1.2. Request factory representative to bring camera toward worker entrance to show:</p> <p>3.1.3. Is there 'No Pets" notice placed at factory main entrance and/or worker entrance to processing area?</p> <p>3.1.4. Is there any physical separation or other segregation between changing area and outside area to prevent environmental contamination and entry of pest?</p> <p>3.1.5. Is the door fitted with self-closing device?</p> <p>3.1.6. Is there sign of pest infestation at changing area?</p> <p>3.1.7. Is social distancing among staffs practiced in the changing area?</p> <p>3.1.8. Is there foot bath level and concentration of sanitizer adequate*? or worker change shoe (*Note: Request factory representative to show how testing is carried out and observed by camera)</p> <p>3.1.9. Is there clear and unclean segregation or demarcation lines or boundary to prevent cross contamination?</p> <p>3.1.10. Is there any pooling of water observed on floor surface of the changing area?</p> <p>3.1.11. Is the floor, wall and ceiling in clean and sound condition at the changing area?</p> <p>3.1.12. Are the outside shoes are kept separating from the processing shoes?</p>	
3.2	<p>Hand Washing Facilities: Request factory representative to bring camera toward hand washing facilities near entrance to processing area to show:</p> <p>3.2.1. Are there hand washing facilities in the changing area or entrance to the processing area?</p> <p>3.2.2. Are the hand washing facilities in clean and sound condition?</p> <p>3.2.3. Are the hand washing taps non-hand operated?</p> <p>3.2.4. Is social distancing among staffs practiced during hand washing?</p> <p>3.2.5. Are the hand washing facilities with "7 steps hand washing" notice?</p> <p>3.2.6. Are the hand washing facilities supply with adequate detergent?</p> <p>3.2.7. Are the hand washing facilities supply with adequate disposable tissue paper?</p>	



3. Changing Area, Hand Washing Facilities and Toilet (continue)		Tick (/) if completed
	3.2.8. Is there foot operated trash bin provided at hand washing facilities?	
	3.2.9. Is there any pooling of water observed on floor surface below the hand washing facilities?	
	3.2.10. Is the floor, wall and ceiling in clean and sound condition at the hand washing facilities?	
	3.2.11. Is the duration of hand washing carried out by workers adequate?	
	3.2.12. Are the hand wash facilities with "minimum duration for hand washing" notice?	
	3.2.13. Is the hand sanitization performed by workers after hand washing?	
	3.2.14. Is there hand sanitization notice?	
3.3	Toilet Facilities: Request factory representative to ensure no occupants in the toilet than ask him or her to bring the camera into the toilet facilities to show:	Tick (/) if completed
	3.3.1. Is the toilet open direct to processing area?	
	3.3.2. Are there hand washing facilities with "7 steps hand washing" notice in the toilet?	
	3.3.3. Are the hand washing facilities in clean and sound condition?	
	3.3.4. Are the hand washing taps non-hand operated?	
	3.3.5. Are the hand washing facilities supply with adequate detergent, disposable tissue paper and foot operated trash bin?	
	3.3.6. Is there any pooling of water observed on floor in the toilet?	
	3.3.7. Is the floor, wall and ceiling in clean and sound condition in the toilet?	
	3.3.8. Are all the toilet bowl in clean and sound condition (in the toilet)?	
	3.3.9. Is the toilet door fitted with self-closing device?	
	3.3.10. Is the lighting adequate in the toilet?	
4. Food Processing Area		Tick (/) if completed
4.1	Segregation of processing activities to prevent cross contamination: Auditor shall obtain soft copy of Process Flow Diagram (PFD) and Factory Plan Layout (FPL) (material and worker flow) prior to conducting site audit remotely. Determine the audit flow from clean processing area to less clean area. Request factory representative to bring the camera as the route determine by the auditor and during remote tour the auditor shall observed and verify evidence for the following:	
	4.1.1. Is there segregation between clean and less clean processing area or zoning of processing area?	
	4.1.2. Is social distancing among staffs practiced in processing area?	
	4.1.3. Are there marking at the workstation in processing area for social distancing purpose?	
	4.1.4. Are the workers stationed as "W" or "V" shape at the workstation?	
	4.1.5. Do worker and material flows as documented in plan layout?	
	4.1.6. Do drain flows from clean to less clean processing area or the drains are totally sealed?	
	4.1.7. Do worker wash their hands and change attire including PPE when move from less clean to clean processing area?	
	4.1.8. Is enough space provided for placement of equipment, storage of materials and for production operations?	
4. Food Processing Area (continue)		Tick (/) if completed
4.2	Packaging Area: Request factory representative to bring the camera as the route determine by the auditor and during remote tour the auditor shall observed and verify evidence for the following for packaging area:	
	4.2.1. Are the floor, wall and ceiling kept in clean and in good repair?	
	4.2.2. Are the lighting adequate and protected from breakage?	
	4.2.3. Are there any pooling of water on floor surface?	
	4.2.4. Are food handling activities or food placed on floor surface?	
	4.2.5. Do the cold chain maintained during packaging (applicable for chill or frozen product only)?	
	4.2.6. Is packaging integrity inspection or test carried out and how? (Note: Request factory representative to zoom camera on packed finish product and verify sealing and labeling information)	
	4.2.7. Are the workers wearing appropriate attire and PPE in packing area to prevent cross contamination?	



4. Food Processing Area (continue)		Tick (!) if completed
4.3	<p>Metal Detector: Request factory representative to bring the camera near to metal detector and observed that:</p> <p>4.3.1. Is the metal detector placed correctly (as stated in process flow diagram) and in working condition?</p> <p>4.3.2. Is there a designated labeled area to place and handle Non-Conforming Products near the metal detector?</p> <p>4.3.3. Interview and request the metal detector operator to test its effectiveness by using test piece. Verify parameter monitored for metal. (Note: verify whether calibration label stick on metal detector and the expiry date)</p>	
4.4	<p>Heat Treatment/Cooking Area/Freezing Area: Request factory representative to bring the camera as the route determine by the auditor and during remote tour the auditor shall observed and verify evidence for the following for Heat Treatment, Cooking and/or Freezing or Chilling Area</p> <p>4.4.1. Are the floor, wall and ceiling kept in clean and in good repair?</p> <p>4.4.2. Are there any pooling of water on floor surface?</p> <p>4.4.3. Are the lighting adequate and protected from breakage?</p> <p>4.4.4. Are there any hanging piping, duct or any other fitting above coking and/or freezing area which can contribute to accumulation of dust or contamination of food product?</p> <p>4.4.5. Is the cooking and/or freezing equipment in clean and sound condition? (Note: Request the factory representative to zoom camera on food contact surface to verify its cleanliness and condition)</p> <p>4.4.6. Are there severe condensation or accumulation of water droplet above coking and/or freezing area which can contribute to food contamination?</p> <p>4.4.7. Is enough space provided for placement of equipment, storage of materials and for production operations?</p> <p>4.4.8. Interview and request the cooking/freezing operator to explain how cooking/freezing is monitored and request his or her to measure product core temperature? (Note: verify whether calibration label stick on cooking/freezing equipment and the expiry date)</p> <p>4.4.9. Are the workers wearing appropriate attire and PPE to prevent cross contamination?</p>	
4.5	<p>Food Preparation Area (Weighing, Cutting, Mixing, Forming etc.): Request factory representative to bring the camera as the route determine by the auditor and during remote tour the auditor shall observed and verify evidence for the following for food preparation area</p> <p>5.1.1. Are food products and processing areas have adequate lighting and protected against contamination from breakage of light bulbs and other glass fixtures</p> <p>5.1.2. Is the floor, wall and ceiling kept in clean and in good repair?</p> <p>5.1.3. Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?</p> <p>5.1.4. Are there any pooling of water on floor surface?</p> <p>5.1.5. Are there any hanging piping, duct or any other fitting above food handling area which can contribute to accumulation of dust or contamination of food product?</p> <p>5.1.6. Are the food contact surface made from durable, easy to clean material, in sound and clean condition?</p> <p>5.1.7. Are waste material placed in foot operated trash bin and removed regularly from food handling area?</p> <p>5.1.8. Are there any sign of pest infestation?</p> <p>5.1.9. Are the workers wearing appropriate attire and PPE to prevent cross contamination?</p> <p>5.1.10. Is the cold chain maintained during food handling including weighing and thawing of frozen product (applicable only for chill and frozen raw material) (Note: Request factory representative to zoom camera on product and request operator to measure temperature. Verify whether calibration label stick on measuring device and the expiry date)</p> <p>5.1.11. Are raw material, ingredient and utensil handled or place on floor surface?</p>	



4. Food Processing Area (continue)		Tick (/) if completed
4.6	<p>Receiving Area: Request factory representative to bring the camera as the route determine by the auditor and during remote tour the auditor shall observed and verify evidence for the following for receiving area</p> <p>4.6.1. Is receiving of raw material, ingredient and packaging material carried out in enclosed area?</p> <p>4.6.2. Is the floor, wall and ceiling kept in clean and in good repair?</p> <p>4.6.3. Is social distancing among staffs practiced in the receiving area?</p> <p>4.6.4. Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?</p> <p>4.6.5. Are there any pooling of water on floor surface?</p> <p>4.6.6. Are there severe condensation or accumulation of water droplet above receiving area which can contribute to food contamination?</p> <p>4.6.7. Are receiving area have adequate lighting and protected against contamination from breakage of light bulbs and other glass fixtures</p> <p>4.6.8. Are food placed on floor surface?</p> <p>4.6.9. Are the workers wearing appropriate attire and PPE to prevent cross contamination?</p> <p>4.6.10. Is raw material, ingredient and packaging material inspected during receiving? (Note: Request factory representative to zoom camera on receiving activity and interview operator hoe the inspection carried out. Verify the measuring device used for measuring such as thermometer is calibrated and with valid calibration labels)</p> <p>4.6.11. Are there any sign of pest infestation?</p>	
5. Storage Facilities		Tick (/) if completed
5.1	<p>Raw material, ingredient and packaging material Storage Area: Request factory representative to bring the camera to each storage area and inspect following:</p> <p>5.1.1. Does all the raw material, ingredient and packaging material have been stored in separate storage rooms or have a clear separation and arranged properly?</p> <p>5.1.2. Is the floor, wall and ceiling kept in clean and in good repair?</p> <p>5.1.3. Are there any hanging piping, duct or any other fitting above storage area which can contribute to accumulation of dust or contamination of food product?</p> <p>5.1.4. Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?</p> <p>5.1.5. Are food or packaging material placed on floor surface or too close to wall surface?</p> <p>5.1.6. Are there any sign of pest infestation?</p> <p>5.1.7. Is First In and First Out (FIFO) in place and practice effectively? (Note: Request factory representative to zoom camera on randomly selected storage product and interview Store Supervisor or operator how FIFO is practice)</p>	
5.2	<p>5.2.1. Finish Product Storage Area (Ambient Temperature): 5.2.2. Request factory representative to bring the camera to each storage area and inspect following:</p> <p>5.2.3. Does all the finish product have been stored in separate storage rooms or have a clear separation and arranged properly?</p> <p>5.2.4. Is the floor, wall and ceiling kept in clean and in good repair?</p> <p>5.2.5. Are there any hanging piping, duct or any other fitting above storage area which can contribute to accumulation of dust or contamination of food product?</p> <p>5.2.6. Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?</p> <p>5.2.7. Are food placed on floor surface or too close to wall surface?</p> <p>5.2.8. Are there any sign of pest infestation?</p> <p>5.2.9. Is First In and First Out (FIFO) in place and practice effectively? (Note: Request factory representative to zoom camera on randomly selected product and interview Store Supervisor or operator how FIFO is practice and check for expired product. Choose a randomly selected finish product and request the Store Supervisor/HACCP Team Member to provide records for traceability)</p>	



5. Storage Facilities (continue)		Tick (!) if completed
5.3	<p>Cold Storage (Freezer or Chiller): Request factory representative to bring the camera to each storage area and inspect following:</p> <p>5.3.1. Does all the raw material, ingredient and finish product have been stored in separate cold storage or have a clear separation and arranged properly?</p> <p>5.3.2. Are food placed on floor surface or too close to wall surface?</p> <p>5.3.3. Is the floor, wall and ceiling kept in clean, in good repair and free from excess ice formation or frost?</p> <p>5.3.4. Are there any food placed direct below refrigeration blower or severe condensation or accumulation of water droplet which can contribute to food contamination?</p> <p>5.3.5. Is First In and First Out (FIFO) in place and practice effectively? (Note: Request factory representative to zoom camera on randomly selected product and interview Store Supervisor or operator how FIFO is practice and check for expired product. Choose a randomly selected finish product and request the Store Supervisor/HACCP Team Member to provide records for traceability)</p> <p>5.3.6. Is the cold room temperature maintained during storage? (Note: Request factory representative to zoom camera on cold room temperature gauge and verify the temperature. Request the HACCP Team member or operator to measure the finish product core temperature. Verify whether calibration label stick on measuring device and the expiry date)</p> <p>5.3.7. Are the Cold Room workers wearing appropriate attire and PPE to prevent cross contamination?</p>	
5.4	<p>Chemical Store: Request factory representative to bring the camera to storage area and inspect chemicals based on information stated in Approve Chemical List obtained from company prior to remote site audit.</p> <p>5.4.1. Does all the chemicals have been stored in separate storage room and arranged properly?</p> <p>5.4.2. Is the floor, wall and ceiling kept in clean and in good repair?</p> <p>5.4.3. Is there any unapproved or unlabeled chemical observed in chemical storeroom?</p> <p>5.4.4. Is there chemical stock card or book available?</p> <p>5.4.5. Is there any expired chemical placed in chemical store?</p> <p>5.4.6. Is the floor, wall and ceiling kept in clean, in good repair?</p> <p>5.4.7. Is the housekeeping well maintained?</p> <p>5.4.8. Is the Chemical Storekeeper competent in term of handling chemical and safety measures? (Note: Request factory representative to zoom camera on randomly selected chemical in storeroom and request the storekeeper to explain how he or she handle the chemical such as when receiving, stock check or if spillage happen)</p> <p>5.4.9. Are there any sign of pest infestation?</p> <p>5.4.10. Is there ventilation in chemical storeroom?</p>	
5.5	<p>Maintenance Store: Request factory representative to bring the camera to each storage area and inspect following: Is the floor, wall and ceiling kept in clean and in good repair?</p> <p>5.5.1. Are there any sign of pest infestation?</p> <p>5.5.2. Is the housekeeping well maintained?</p> <p>5.5.3. Are all the lubricant and grease used for machine in factory are food grade?</p> <p>5.5.4. Is the maintenance supervisor or worker competent in term repairing and maintenance of machinery and equipment in the factory? (Note: Note: Request factory representative to zoom camera at selected maintenance supervisor or staff and interview him or her for qualification/training certificate and how maintenance work is carried out)</p>	
5.6	<p>Water Storage for Processing: Request factory representative to bring the camera to water storage area and inspect following:</p> <p>5.6.1 Is the water tank properly closed and not exposed to contamination from outside?</p>	

END OF GUIDELINE TO CONDUCT SITE AUDIT REMOTELY



PANDUAN MENJALANKAN AUDIT DOKUMENTASI SECARA REMOTE

		FOOD SAFETY AND QUALITY DIVISION MINISTRY OF HEALTH MALAYSIA	FORM 2-REMOTE
GUIDELINE TO CONDUCT DOCUMENTATION AUDIT REMOTELY			
Factory Name:			
Date of Remote Audit:			
1.0 General Requirements for HACCP Documentation: The auditor should request soft copy in pdf format of HACCP Manual uploaded in google drive or shared during remote audit. The auditor should check HACCP Manual for following information and evidence:			Tick (/) if completed
1.1	HACCP Manual Cover Page for Company Name, approved date and revision number		
1.2	Amendment log for changes in documentation and table of content		
1.3	Top management commitment clearly expressed in its food safety policy and objectives		
1.4	Scope of HACCP system specific to product and production site from the beginning to the end.		
1.5	HACCP team: responsibilities documented and updated		
1.6	HACCP team: Adequate qualification and experience available (Note: Request CV of HACCP Team members uploaded in google drive or shared during remote audit)		
2.0 Product Description: The auditor should request soft copy in pdf format of HACCP Manual uploaded in google drive or shared during remote audit. The auditor should check HACCP Manual for following information and evidence:			Tick (/) if completed
2.1	Products description clear and complete for each product or processes?		
2.2	Include origin and specifications of raw material		
2.3	Include composition, packaging, distribution, validity, storage condition		
2.4	Include additives and/or ingredients in the final product.		
3.0 Users/ Consumers: The auditor should request soft copy in pdf format of HACCP Manual uploaded in google drive or shared during remote audit. The auditor should check HACCP Manual for following information and evidence:			Tick (/) if completed
3.1	Sensitive consumers identified?		
3.2	Instructions given for the distribution, storage, prevention of consumer abuse and utilization		
4.0 Processing Specification: The auditor should request soft copy in pdf format of HACCP Manual uploaded in google drive or shared during remote audit. The auditor should check HACCP Manual for following information and evidence:			Tick (/) if completed
4.1	Flow diagram includes each stage of processing chain		
4.2	Flow diagram verified by HACCP Team Member other than the person who documented it.		



5.0 Hazard Identification and Analysis: The auditor should request soft copy in pdf format of Hazard Analysis Worksheet under the HACCP System scope uploaded in google drive or shared during remote audit. The auditor should check the Hazard Analysis Worksheet in the HACCP Manual for following information and evidence:		Tick (/) if completed
5.1	Includes Ph, Ch and Bi ¹ hazards associated to raw materials	
5.2	Includes Ph, Ch and Bi hazards associated to each step of processing	
5.3	Hazards evaluated in terms of likelihood and severity	
5.4	Includes references, bibliography or external advice used on the analysis	
5.5	Identifies potential process and staff variations	
5.6	Preventive measures identified to control each relevant risk.	
5.7	Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;	
6.0 Determination of Critical Control Point (CCP): The auditor should request soft copy in pdf format of updated Hazard Analysis Worksheet under the HACCP System scope uploaded in google drive or shared during remote audit. The auditor should check the Hazard Analysis Worksheet in the HACCP Manual for following information and evidence:		Tick (/) if completed
6.1	The Identification is consistent with the identified hazards and CCP's are correctly identified	
6.2	It includes references to methodologies and resources used	
6.3	Control measures were identified for each CCP	
7.0 Adoption of Critical Limits: The auditor should request soft copy in pdf format of updated HACCP Plan Summary and critical limits validation reports are uploaded in google drive or shared during remote audit. The auditor should check the HACCP Plan Summary in the HACCP Manual and validation reports for following information and evidence:		Tick (/) if completed
7.1	Critical limit established for each CCP	
7.2	Are the CLs able to be reduce the significant hazard to acceptable level to ensure safety of finish product?	
7.3	Are critical limits validated considering published/experimental evidence	
8.0 Monitoring of CCP: The auditor should request soft copy in pdf format of updated HACCP Plan Summary and CCP monitoring records are uploaded in google drive or shared during remote audit. The auditor should check the HACCP Plan Summary in the HACCP Manual and CCP monitoring records for following information and evidence:		Tick (/) if completed
8.1	Responsibilities and activities documented for each CCP.	
8.2	Includes <i>what, who, when, where</i> and <i>how</i> each CCP is monitored	
8.3	Includes verifiable records and identification of the responsibilities	
8.4	CCP records are available and verified by HACCP Team Member	
9.0 Corrective Actions if CCP Deviate: The auditor should request soft copy in pdf format of updated HACCP Plan Summary and corrective action records are uploaded in google drive or shared during remote audit. The auditor should check the HACCP Plan Summary in the HACCP Manual and corrective action records for following information and evidence:		Tick (/) if completed
9.1	Corrective Action responsibilities and activities documented for each CCP.	
9.2	Includes <i>what, who, when, where</i> and <i>how</i> corrective actions are taken on the system and non-conformance products	
9.3	Are documented corrective action realistic and cover destination of non-conforming products	
9.4	Are documented corrective action includes measures or action to avoid re-occurrence?	



10.0 Verification Procedures:		Tick (/) if completed
The auditor should request soft copy in pdf format of updated HACCP Plan Summary and verification records such as finish product laboratory test results, measuring device calibration certificate and other verification activities records are uploaded in google drive or shared during remote audit. The auditor should check the HACCP Plan Summary in the HACCP Manual and verification activities records for following information and evidence:		
10.1	Responsibilities and activities documented for each CCP.	
10.2	Includes what, who, when, where and how verification activities take place	
10.3	Includes final product testing and calibration of equipment	
10.4	Includes action in case that verification shows non compliances	
10.5	Review of the HACCP plan	
11.0 Documentation and Records:		Tick (/) if completed
The auditor should request soft copy in pdf format of updated HACCP Plan Summary and list of records are uploaded in google drive or shared during remote audit. The auditor should check the HACCP Plan Summary in the HACCP Manual and records for following information and evidence:		
11.1	Records are documented for each component of the HACCP plan.	
11.2	Includes what, who, when, where and how records are taken and stored	
12.0 Revision of HACCP System:		Tick (/) if completed
The auditor should request soft copy in pdf format of updated HACCP is uploaded in google drive or shared during remote audit. The auditor should check the updated HACCP Manual and records for following information and evidence:		
12.1	Changes and Modifications	
	12.1.1 Changes or modification in process -raw materials included in the revision plan	
	12.1.2 HACCP Plan revised as required in the standards	
12.2	Documentation and Records	
	12.2.1 Records are available in their respective areas and updated	
	12.2.2 Records can be traced and reviewed as far as the last regulatory verification	
12.3	Management of the Plan	
	12.3.1 Preventive measures followed and verifiable?	
	12.3.2 Monitoring procedures followed and verifiable?	
	12.3.3 Corrective actions followed and verifiable?	
	12.3.4 Verifications activities followed and verifiable?	
13.0 General Requirements for Pre-Requisite Program Documentation and Records:		
The auditor should request soft copy in pdf format of PRP Manual/Procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence. (Note: Determination of which PRP procedures and records to be remotely audited should be based on evidence gathered during remote site audit or pre-determined prior to audit and communicated with auditee)		
13.1	PRP Manual Cover Page for Company Name, approved date and revision number	
13.2	Amendment log for changes in documentation and table of content	
13.3	Factory plan layout (general layout, equipment and sanitary facilities, worker and material flow, pest control activities and hygiene zoning.	
13.4	Design and Facilities	
The auditor should request soft copy in pdf format of Design and Facilities procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:		
13.4.1.	Are documented procedures available for location, premises and rooms, equipment and facilities.	
13.4.2.	Are records available to evaluate effectiveness of design and facilities element.	
13.4.3.	Are design and facilities element effectively implemented?	
13.4.4.	(Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	



13.5	<p>Control of Operation The auditor should request soft copy in pdf format of Control of Operation procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:</p>	Tick (/) if completed
13.5.1.	Are documented procedures available for control of food hazards, key aspects of hygiene control systems, incoming materials requirements, packaging, water, management and supervision, control of documents and records, traceability system and product recall.	
13.5.2.	Are records available to evaluate effectiveness of process control activities including traceability and recall procedures.	
13.5.3.	Is process control element effectively implemented? (Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	
13.6	<p>Maintenance, Cleaning and Sanitization The auditor should request soft copy in pdf format of Maintenance, Cleaning and Sanitization procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence from the documented procedures and records:</p>	Tick (/) if completed
13.6.1.	Are documented procedures available for maintenance and cleaning, pest control activities and waste management	
13.6.2.	Are records available to evaluate effectiveness of maintenance and cleaning, pest control activities and waste management.	
13.6.3.	Are maintenance and cleaning, pest control activities and waste management effectively implemented?	
13.6.4.	(Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	
13.7	<p>Personal Hygiene The auditor should request soft copy in pdf format of Personal Hygiene procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:</p>	Tick (/) if completed
13.7.1.	Are documented procedures available for worker health status, personal cleanliness, personal behaviour and visitor health and hygiene requirements.	
13.7.2.	Are records available to evaluate effectiveness of worker health status, personal cleanliness, personal behaviour and visitor health and hygiene	
13.7.3.	Are workers health status, personal cleanliness, personal behaviour and visitor health and hygiene effectively implemented?	
13.7.4.	(Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	
13.8	<p>Transportation and Distribution The auditor should request soft copy in pdf format of Transportation and Distribution procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:</p>	Tick (/) if completed
13.8.1.	Are documented procedures available for Transportation and Distribution.	
13.8.2.	Are records available to evaluate effectiveness Transportation and Distribution	
13.8.3.	Are Transportation and Distribution element effectively implemented?	
13.8.4.	(Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	
13.9	<p>Product Information The auditor should request soft copy in pdf format of Product Information procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:</p>	Tick (/) if completed
13.9.1.	Are documented procedures available for lot and batch identification, product information and labelling.	
13.9.2.	Are records available to evaluate effectiveness lot and batch identification, product information and labelling.	
13.9.3.	Are lot and batch identification, product information and labelling. effectively implemented? (Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	



13.10	Training The auditor should request soft copy in pdf format of training procedures and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:	Tick (/) if completed
	13.10.1. Are documented procedures available for training including training need analysis, yearly training schedule and training evaluation.	
	13.10.2. Are records available to evaluate effectiveness of training and evidence training carried out. Is the training effective? (Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	
13.11	Internal Inspection The auditor should request soft copy in pdf format of Internal Inspection and records are uploaded in google drive or shared during remote audit. The auditor should check for following information and evidence:	Tick (/) if completed
	13.11.1. Are documented procedures available for internal inspection and internal audit?	
	13.11.2. Are records available for internal inspection and internal audit?	
	13.11.3. Is internal audit carried out by trained personal and impartiality maintained? (Note: The auditor should justify effectiveness of the element based of evidence gathered during remote site inspection results and conclusion from records checks)	
	13.11.4. Are the audit findings documented, Non-Compliance Request (NCR) issued for non-conformance detected and adequately closed?	
13.12	Management Review The auditor should request soft copy in pdf format of the latest Management Review Meeting Minute check for following information and evidence:	Tick (/) if completed
	13.12.1. Does the minute discuss follow-up action from previous management review meeting?	
	13.12.2. Does the minute discuss analysis of results of verification activities including internal audit, external audit and inspections?	
	13.12.3. Does the minute discuss changing circumstances that can affect food safety?	
	13.12.4. Does the minute discuss emergency situations, accidents and recall?	
	13.12.5. Does the minute discuss reviewing results of system updating activities?	
	13.12.6. Does the minute discuss review of communication activities, including authorities, customer feed-back and complaints; and	
	13.12.7. Does the minute discuss review of PRP activities	
14.0	Prevention of COVID-19 The auditor should request soft copy in pdf format of the latest SOP for prevention and control of COVID-19	
	13.13.1 Is there SOP for prevention of COVID-19?	
	13.13.2 Is there training record on prevention of COVID-19?	
	13.13.3 Is there record for disinfection at common area 3 times per day?	
	13.13.4 Is there record of COVID-19 vaccination for workers?	

END OF GUIDELINE TO CONDUCT DOCUMENTATION AUDIT REMOTEL



KEMENTERIAN KESIHATAN MALAYSIA
BAHAGIAN KESELAMATAN DAN KUALITI MAKANAN

Disediakan oleh:
Kementerian Kesihatan Malaysia
Bahagian Keselamatan dan Kualiti Makanan
Cawangan *Pre-Market Approval*
Seksyen Pembangunan Juruaudit