

What is **SMETA**

SMETA is an audit, which helps you to understand standards of **labour, health and safety, environmental performance, and ethics** within your own operations or at a supplier site.

It is designed to help protect workers from **unsafe conditions, overwork, discrimination, low pay and forced labour.**



Isofield® joins Sedex in commitment to social and environmental sustainability



Kuala Lumpur 01st June 2023

Isofield has become a Sedex member, joining the world-leading organisation in their latest commitment to social and environmental sustainability.

Isofield is dedicated to being a responsible business, managing their operations and supply chain in a way that safeguards workers, communities and the environment. Joining Sedex supports Isofield's established ethical sourcing/CSR/sustainability programme.

Sedex's technology and services help companies such as Isofield to source more responsibly. The platform and solutions provided empower companies with the practical tools, data analysis and business insights needed to operate ethically, source sustainably, and work with suppliers to protect people and the environment.

Isofield will use Sedex technology and data tools to collaborate with *our supply chain in more detail, integrating risk assessment, audit and worksite data to better understand working conditions and facilitate positive impacts amongst key stakeholders in our sphere of influence.*

From Stephen Morgan, Managing Director "Sincere thanks to the quality, production, and HR teams who worked tirelessly over the past number of months to make this happen and who have done an outstanding job. Thanks also to the auditors at BSI who facilitated the work and ensured a full agenda was professionally executed."

"Sedex is delighted to welcome Isofield as a member. We welcome their commitment to responsible business, and look forward to supporting them to achieve their social and environmental sustainability goals."

Jon Hancock, CEO, Sedex

About Sedex

Sedex is a world leader in responsible sourcing and empowers companies to implement responsible business practices and policies in their business and supply chain to build responsible supply chains.

Sedex provides businesses with the tools, technology and insights needed to operate ethically, source responsibly and work with their suppliers to create fair working conditions for the people who make their products and services. Over 65,000 businesses use Sedex to manage business risk, meet compliance and drive positive impacts for people and the environment. Visit our [website](#) for more information.

Why is SMETA important?

Increased visibility

Gain a greater understanding of the social and environmental performance of your business and suppliers

Priorities high risks

Assess and monitor higher risk suppliers on their performance over time

Efficient supplier auditing

Data can be shared with multiple buyers, reducing the number of audits you'll need to collect

Improve supplier performance

SMETA provides a Corrective Action Plan to help improve supplier performance and resolve issues found in the audit

Comply with legislation

SMETA audits facilitate compliance with existing and upcoming legislation

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Difference between SMETA & ISO 9001

Social Compliance Vs Management Systems

- Social compliance audits are sometimes also called social audits, ethical audits or social accountability audits. Importers rely on this type of factory audit to **verify and monitor their supplier's working conditions** for compliance with international labor standards.
- ISO 9001 is a globally recognized quality management standard issued by the International Organization for Standardization (ISO).
- A typical ISO 9001 quality system audit includes evaluating:
 - Basic facilities, environment and equipment maintenance
 - Quality management system organization
 - Incoming quality controls for materials and components
 - During production controls to identify quality issues
 - Finished goods controls and inspection
 - Lab testing capabilities
 - HR recruitment and training practices
 - Engineering, research and design capabilities
 - Business development and management behavior

Overview

Sedex
Virtual Assessment

Sedex Virtual Assessment Reference: URN 2023MYZAA423776238 Sedex Virtual Assessment Report Version 1.0

Sedex²
Virtual Assessment

Sedex Virtual Assessment Report
Version 1.0.



Audit Company: BSI GROUP
Report Reference: ZAA423776238
Date: 12 May 2023

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1. Assessment Overview

	Site Assessed
1.1 Sedex Company Reference: (only available on Sedex System)	ZC: 421635019
1.2 Sedex Site Reference: (only available on Sedex System)	ZS: 421687154
1.3 Business name (Company name):	ISOFIELD SDN BHD
1.4 Site name:	ISOFIELD SDN BHD
1.5 Site address: (Please include full address)	No. 6, Jalan Gudang 16/9, Seksyen 16, Shah Alam, Selangor – 40200, Malaysia
1.6 Country:	Malaysia
1.7 Site contact and job title:	Mr. Steve Morgan, Managing Director
1.8 Site phone:	+603 5512 1709
1.9 Site email:	steve.morgan@isofield.com
1.10 Name and Title of person who signed CAPR (if different from above)	Mr. Sua, Yi Chen, Quality Manager
1.11 Sedex Virtual Assessment Pillars: (Please delete as necessary)	4 Pillar
1.12 Sedex Virtual Assessment type: (Please delete as necessary)	Initial

Audit Company Name, Logo & Reference Number:

BSI Group



SVAZC1021464

Report Owner (payer):

(If paid for by the customer of the site please remove for Sedex upload)

ISOFIELD SDN BHD

Worker sampling & Interviews

Conditional Considerations Review	
2.5. Please describe any additional considerations which affected how the methodology was completed:	No additional considerations.
2.6. Scope of Assessment (please mark any deviation/omission from the Sedex Virtual Assessment Technical Requirements):	The scope of assessment covered all the requirements of SVA and nothing was omitted.
Methodology	
2.7. Was the SAQ accessed and reviewed as a part of the assessment preparation?	Yes
2.8. Please provide a list of documents reviewed as part of the assessment preparation	Policies, Procedures, Legal documents, Test reports, Formats
2.9. Level of digitization at the site (low, medium high)	High: mostly all digital
2.10. Sample Size Checked (State number of worker records checked and from which weeks/months - should be current, peak, and random/low. Please see SMETA Best Practice Guidance and Measurement Criteria)	Sample size checked was 12 workers. Sampled months: June 2022 (peak month), January 2023 (random month), April 2023 (low month)
2.11. % time spent in preparation including pre-assessment document reviews (offline)	20
2.12. % time spent in assessment (online)	80
2.13. Please advise of any technology failures (either partial or whole) encountered during the assessment	Nil
2.14. Please advise of any operational failures (either partial or whole) encountered during the assessment.	Nil
2.15. Detailed site map provided (please attach in appendix)	Yes
2.16. Please list all software used during the assessment	MS Teams & Whatsapp
Direct Worker Engagement	
2.17. Please select methods of worker engagement used (Delete as applicable)	Group Interviews
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2.18. Total number of workers interviewed: (Only complete if group worker interviews were conducted as a part of the assessment)	4 Groups of 3
Women / Men	6 / 6
Contract / Direct	0 / 12
Local / Domestic Migrant / Foreign Migrant	12 / 0 / 0
Service providers	1 (security guard)
Union / Worker reps	None
2.19. Total response rate for Direct Worker Reporting/ Worker Voice (Only complete if Direct Worker Reporting or Worker Voice was used to support the assessment)	Not applicable
Women / Men	Not applicable
Contract / Direct	Not applicable
Local / Migrant	Not applicable
2.20. Please provide a summary of the methodology used to collect Direct Worker Reporting/ Worker Voice	Not applicable
2.21. Please advise how Direct Worker Reporting/ Worker Voice results were used to inform the assessment.	Not applicable
2.22. Summary of workers key priorities at the site: (To be completed for all methods used)	No complaints or issues were raised by interviewed workers. One worker suggested for the company to have a vending machine for snacks and coffee.

No Complaints or issues were raised by interviewed workers

Worker makeup & Turnover

Low (5.9%) Churn

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4. Worker Analysis

	Worker Profiles										Total
	Local Workers			Domestic Migrant Workers			Foreign Migrant Workers			Home workers	
	Permanent	Temporary	Agency	Permanent	Temporary	Agency	Permanent	Temporary	Agency		
Worker numbers – Male	19	0	0	0	0	0	0	0	0	0	49
Worker numbers – Female	22	0	0	0	0	0	0	0	0	0	22
Total	41	0	0	0	0	0	0	0	0	0	41

Assessment attendance	
41. Nationality of management	Ireland
42. Number of nationalities on site:	one
43. Please list the 3 most common nationalities amongst the workforce:	
Nationality 1 / % of total workforce	Malaysian / 100%
Nationality 2 / % of total workforce	Not applicable
Nationality 3 / % of total workforce	Not applicable

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100% Malaysian Workforce

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5. Workplace Impact

	Workplace Impact
5.1. Annual Worker Turnover	5.90%
5.2. Annual Absenteeism	January-April 2023: 101 mandays
5.3. Accidents log available	Yes
5.4. Annual lost days to sickness/accidents per 100 workers	0
5.5. % workers who work > 48 hours per week n the last 6 / 12 months:	87
5.6. % workers who work > 60 hours per week n the last 6 / 12 months:	0

6. Details by Clause

oA: Universal Rights covering UNGP

Current Systems and Evidence Examined
To complete 'current systems' Auditors examine policies and written procedures in conjunction with relevant managers, to understand, and record what controls and processes are currently in place e.g. record what policies are in place, what relevant procedures are carried out, who is /are responsible for the management of this item of the code. Evidence checked should detail any documentary or verbal evidence shown to support the system.

Current systems:

Facility implements and maintains systems for delivering compliance to this code. Mr. Steve Morgan and Mr. Sua Yi Chen are responsible for compliance with the code and appointed as Senior Management Representative. The site has identified the list of stakeholders and the potential/adverse impacts on human rights. The system of confidentiality reporting is ensured, and one complaint box is provided near the rest area.

Evidence examined – to support system description (Documents examined & relevant comments. Include renewal/ expiry date where appropriate):

Freedom of Employment & Safety

1: Freely Chosen Employment

To complete 'current systems' Auditors examine policies and written procedures in conjunction with relevant managers, to understand, and record what controls and processes are currently in place e.g. record what policies are in place, what relevant procedures are carried out, who is /are responsible for the management of this item of the code. Evidence checked should detail any documentary or verbal evidence shown to support the system

Current systems:

- The facility's Prevention of Forced Labour Policy states that the company strictly prohibits the use of forced labour or compulsory labour including prison labour and does not tolerate or condone any form of forced labour, that the company does not require any employees or persons to pay "deposits" to the Company upon commencing employment, and that employees shall have the right to leave the workplace premises after completing the standard workday and be free to terminate their employment if they give reasonable notice to the company.
- There is no evidence found of forced, bonded or involuntary prison labor used in this facility.
- 12 sampled workers interviewed informed that they are not required to lodge deposits or identity documents with their employer and are free to leave their employer after reasonable notice.
- Employees are free to resign from the company at any time subject to requirement of advance notice given as per local law regulations.
- Equal opportunity is given to all employees on the basis of their demonstrated capability, qualification, experience and potential.
- During employees' interview, it was noted that employees were working voluntarily and employees did not appear to be under pressure.
- Employees' freedom of movement is not impeded once their shifts end and no restriction of movement to liberties such as washroom, meal break and tea break.

Evidence examined – to support system description (Documents examined & relevant comments. Include renewal/expiry date where appropriate):

Details:

- Management interviews
- Worker interviews
- Site observation
- Document review:
 - Prevention of Forced Labour Policy, doc. no. Isofield-POL-HR-006, Rev.0, Dated 23/11/22
 - Personnel files and employment contracts for 12 sampled workers

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3: Working Conditions are Safe and Hygienic

To complete 'current systems' Auditors examine policies and written procedures in conjunction with relevant managers, to understand, and record what controls and processes are currently in place e.g. record what policies are in place, what relevant procedures are carried out, who is /are responsible for the management of this item of the code. Evidence checked should detail any documentary or verbal evidence shown to support the system

Current systems:

Mr. Yee, Chon Fat, Operations Manager is responsible for Environmental, Safety & Health.
Potable water was freely available in all floors.
There were at least 2 exits from each work area and these were clearly marked
Fire-fighting equipment was adequate and checks were up-to-date.
Evacuation diagrams were posted in all areas and understood by all workers interviewed
Firefighting and fire drill report dated 04.11.2022 and 39 employees had participated.
Fire equipment maintenance record dated 17.03.2023, 18.04.2023 and 11.05.2023 by external agency, M/s. Menang Technic Engineering SDN. BHD.
Site risk assessment, ISOfield-EHS-004, Rev. No. 01 dated 01.01.2023 for loading, Packing, packing, printing, forklift, etc.
Verified the training plan for the year 2022 & 2023.
On the job training for washer machine operations dated 18.04.2023 imparted to 3 personnel and dryer machine operations dated 18.04.2023 imparted to 3 personnel, packing training dated 21.02.2023 imparted to 12 personnel, bulk packing training dated 14.02.2023 imparted to 12 personnel, light table training dated 16.01.2023 imparted to 10 personnel, material handling training dated 04.01.2023 imparted to 3 personnel, sealing training dated 22.03.2023 imparted to 7 personnel.
Evidenced the list of applicable laws and regulations, ISOfield-ML-011, Rev. No. 00 dated 21.11.2022.
Visit note dated 11.01.2022 and 23.02.2022 by Department of Occupational Safety and Health Selangor.
Verified the first aid log, ISOfield-HR-010, Rev. No. 01 dated 22.02.2023. Two minor injuries were reported.
Evidenced the list of chemicals used, ISOFIELD-ML-009, Rev. No. 00 dated 08.11.2022.

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- No evidence of forced, bonded, ...or involuntary labour
- Equal Opportunity given to ALL employees
- Freedom of movement is not impeded



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Emergency preparedness and response procedure, ISOFIELD-QSOP-EHS-01, Rev. No. 00 dated 17.11.2022.
Fire extinguishers – Dry Powder (9 kgs) – 26, Co2 (2 kgs) – 18. Fire hose reels – 8 numbers, Fire hydrants – 3 numbers, Fire alarms – 8 numbers, Smoke detectors – 3 numbers, Sprinkler points – 495 numbers, Drinking water points – 1 number, Toilets – 3 (Male – 1, Female – 1, Common – 1), Urinals – 2, Sprinkler tank capacity – 35200 Gal. Hose reel tank capacity – 3200 Gal.
Health & Safety committee meeting minutes dated 01.12.2022 and 13.03.2023.

Living wages & Working hours

5: Living Wages are Paid

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Current systems:

- The facility pays monthly wages at the end of the month directly to the employees into their personal bank account and confirmed from wage payment records and worker interviews. No advance payment made.
- Review of sampled workers pay roll records show no workers are being paid below the minimum wage which is RM1500/month and overtime payments and deductions are being made in accordance with local law
- Employees are paid on monthly basis through bank in and are provided with written and understandable detailed wage slips that stated the standard required information - basic wages, overtime hours, overtime wages, allowances received, deductions made
- No deductions for disciplinary issues are made as confirmed from pay slips and worker interviews.
- All interviewed workers confirmed that over time (OT) work is voluntary and they were aware about the premium and normal OT rate calculation
- Statutory deductions such as Employee Provident Fund (EPF), Social Security (SOCSO) and Employee Insurance Scheme (EIS) were found applied to all local employees' monthly wages.
- Records of payment of statutory deductions on monthly basis to local authorities are maintained.
- Workers interviewed confirm they have documented employment agreements, they understand the terms and conditions of their employment and receive their pay each month on time. Workers also confirmed no deductions for disciplinary issues are made.
- The company provided additional incentives not required by local law to specific workers, including travel allowance and acting supervisor allowance. This is noted as a good example.

6: Working Hours are not Excessive

To complete 'current systems' Auditors examine policies and written procedures in conjunction with relevant managers, to understand, and record what controls and processes are currently in place e.g. record what policies are in place, what relevant procedures are carried out, who is /are responsible for the management of this item of the code. Evidence checked should detail any documentary or verbal evidence shown to support the system

Current systems:

- The factory uses a fingerprint time recording system to record working hours. Workers were observed clocking their attendance during arrival and departure.
- Working hours differ for office staff and production workers as follows:
 - Office staff: Monday - Friday, 8:30am - 5:30pm
Break times: One hour (flexible hours)
 - Production staff: Monday - Saturday, 8:00am - 4:00pm with maximum overtime until 8pm (4 hours)
Break times: Morning break: 9:30am - 9:45am and 9:45am - 10:00am (15 mins)
Lunch break: 1:00pm - 1:30pm and 1:30pm - 2:00pm (30 mins)
Additional 15 minutes tea break is allowed for workers working overtime.
No night shift is performed.
- Overtime is paid accordingly to the legal premium. Additional hours of work done beyond the normal working hour is classified as overtime and compensated at the premium rate. i.e. 1.5 x of hourly rate of pay on weekdays, 2.0 x of hourly rate of pay on off days, 2.0 x of hourly rate of pay for first 8 hours of work on public holidays and 3.0 x of hourly rate of pay for any work done after first 8 hours on public holidays.
- Minimum of 11 public holidays are given to employees in one calendar year, which is in accordance with the minimum legal requirement of 11 gazetted public holidays.
- For sampled working hours records for months of June 2022, January 2023 and April 2023, found 50% of 12 sampled workers worked over 60 hours/week in month of June 2022 only, up to a maximum of 64

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hours/ week. For other sampled months, no other workers were found working over 60 hours/week. As per management information, the company implemented the 60 hour work week as of July 2022, and hence will continue to implement this policy.

Evidence examined – to support system description (Documents examined & relevant comments. Include renewal/ expiry date where appropriate):

Details:

- Management interviews
- Worker interviews
- Onsite observation: Fingerprint time recording system
- Document review:
 - Working hours records and pay slips for 12 sampled workers for months of June 2022, January 2023 and April 2023
 - Annual leave records / sick leave records

- No workers paid under min wage
- All Overtime is voluntary
- All Statutory payments made
- Additional incentives given

Migrant workers & Overtime

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G: Any local waivers/local law or permissions which allow averaging/annualised hours for this site? NA

Overtime Hours worked

H: Actual overtime hours worked in sample (State per day/week/month) Highest OT hours:
June 2022: 4 OT hours/day, 64 total hours/ week, 81 OT hours/month
January 2023: 4 OT hours/day, 60 total hours/ week, 46 OT hours/month
April 2023: 4 OT hours/day, 60 total hours/ week, 23 OT hours/month

I: Combined hours (standard or contracted + overtime hours - total) over 60 found? Please give details: Yes
50% of work weeks for 12 sampled workers for month of June 2022 was found to be over 60 hours a week.
For sampled months of January 2023 and April 2023, no workers were found to be working over 60 hours a week.

J: Approximate percentage of total workers on highest overtime hours: 33.33%

K: Is overtime voluntary? Yes
*K1: Please detail evidence e.g. Wording of contract / employment agreement / handbook / worker interviews / refusal arrangements:
Voluntary overtime is confirmed from worker interviews.*

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A: Were all workers presented with terms of employment at the time of recruitment, did they understand them and are they same as current conditions? Terms & Conditions presented
 Understood by workers
 Same as actual conditions

A1: If any are unchecked, please describe finding and specific category(ies) of workers affected:

B: Did workers' pay any fees, taxes, deposits or bonds for the purpose of recruitment/placement? No
B1: If yes, please describe details and specific category(ies) of workers affected: N/A

C: If yes, list all that apply: (please delete as necessary) N/A

D: If any checked, give details: N/A

Migrant Workers:
The term "migrant worker" refers to a person who is engaged or has been engaged in a remunerated activity in a country of which they are not a national or permanent resident or has purposely migrated on a temporary basis to another in-country region to seek and engage in a remunerated activity

A: Type of work undertaken by migrant workers: Not applicable as the company has no migrant workers.

B: Please give details about recruitment agencies for migrant workers: B1: Total number of (in country recruitment agencies) used: Nil
B2: Total number of (outside of local country) recruitment agencies used: Nil

C: Are migrant workers' voluntary deductions (such as for remittances) confirmed in writing by the worker and is evidence of the transaction supplied by the facility to the worker? No
C1: Please describe finding: Nil
C2: Observations: Not applicable as the company has no migrant workers.

D: Are any migrant workers in skilled, technical, or management roles? No
D1: If yes, number and example of roles: N/A

Migrant Workers (this should include all migrant workers including permanent workers, temporary and/or seasonal workers)

Humane treatment & Business ethics

9: No Harsh or Inhumane Treatment is Allowed

Current Systems and Evidence Examined

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Current systems:

- The facility's Workplace Harassment Prevention Policy states that the company does not tolerate the harassment of its employees in the workplace and harassment means any verbal, written or physical conduct that is known or ought reasonably to have been known to be unwelcome, inappropriate or otherwise offensive to a person, and that such conduct demeans, humiliates, threatens him/her or otherwise violates his/her dignity.
- Section 6.0. Sexual Harassment of the facility's Code of Conduct states the type of sexual harassment prohibited by the company.
- The Workplace Harassment Prevention Policy defines the Disciplinary Measures, Restitution and Appeal procedures to address any employee misconduct including harassment and abuse and sexual harassment.
- Workers interview evidence that there is no harsh, inhumane treatment or other kind of harassment imposed by the management against them throughout their employment.
- Workers further added they were treated fairly with full respect by the facility management.

Evidence examined – to support system description (Documents examined & relevant comments. Include renewal/ expiry date where appropriate):

Details:

- Management interviews
- Worker interviews
- Document review:
 - Workplace Harassment Prevention Policy, doc. no. Isofield-POL-HR-013, Rev.0, dated 1/1/2023
 - Section 6.0. Sexual Harassment, Code of Conduct, doc. no. Isofield-POL-HR-009, Rev.0, Dated: 1/1/2023

Any other comments:
Nil

10C: Business Ethics – 4-Pillar Assessment

To complete 'current systems' Auditors examine policies and written procedures in conjunction with relevant managers, to understand, and record what controls and processes are currently in place e.g. record what policies are in place, what relevant procedures are carried out, who is /are responsible for the management of this item of the code. Evidence checked should detail any documentary or verbal evidence shown to support the system

Current systems:

- The facility's Anti-Bribery & Anti-Corruption Policy states that the company is committed to conducting its business based on principles of fairness, honesty, openness, decency, integrity and respect, and the company is focused on fostering a business environment with high standards of integrity in all its conduct as well as business practices and adopts a zero-tolerance policy against all forms of bribery and corruption to achieve a higher level of professionalism in reaching corporate governance and social responsibility.
- Ms. Anna Tan / HR Manager is the person in charge for implementing the Code of Ethics, and the code is communicated to all employees and staff, business partners, suppliers and vendors.
- Employees are briefed on the ethical conduct policies upon hiring.

Evidence examined – to support system description (Documents examined & relevant comments. Include renewal/ expiry date where appropriate):

Details:

- Management interviews
- Worker interviews
- Document review:
 - Anti-Bribery & Anti-Corruption Policy, doc. no. Isofield-POL-HR-012, Rev.0, dated 1/1/2023

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Workers say there is no harsh, inhumane treatment or any kind of harassment

Workers state they are treated fairly and with FULL respect by management

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Worker Makeup & Turnover

Freedom of Employment & Safety

Living Wages & Working Hours

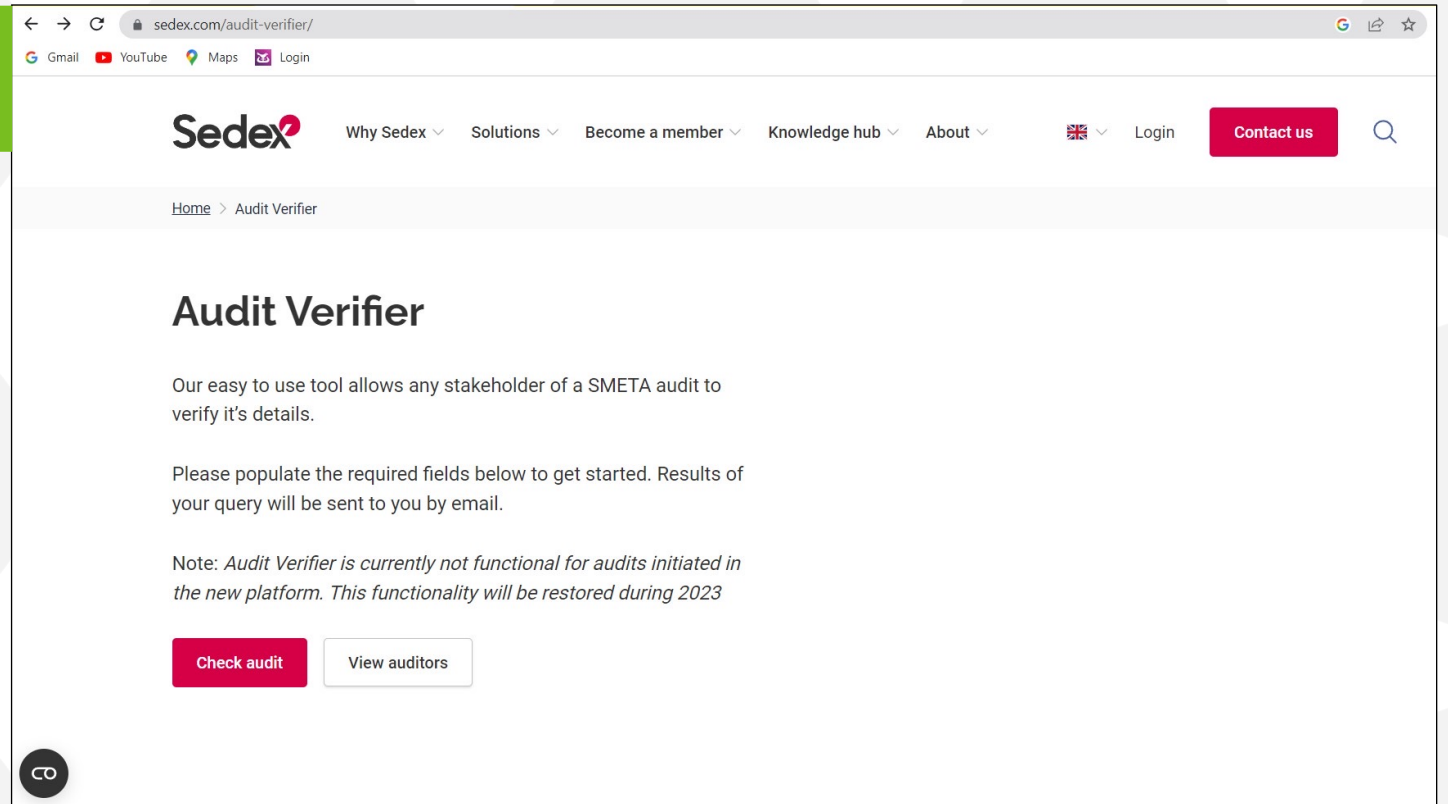
Migrant Workers & Overtime

Humane Treatment & Business Ethics



Check & Verify Audit Online

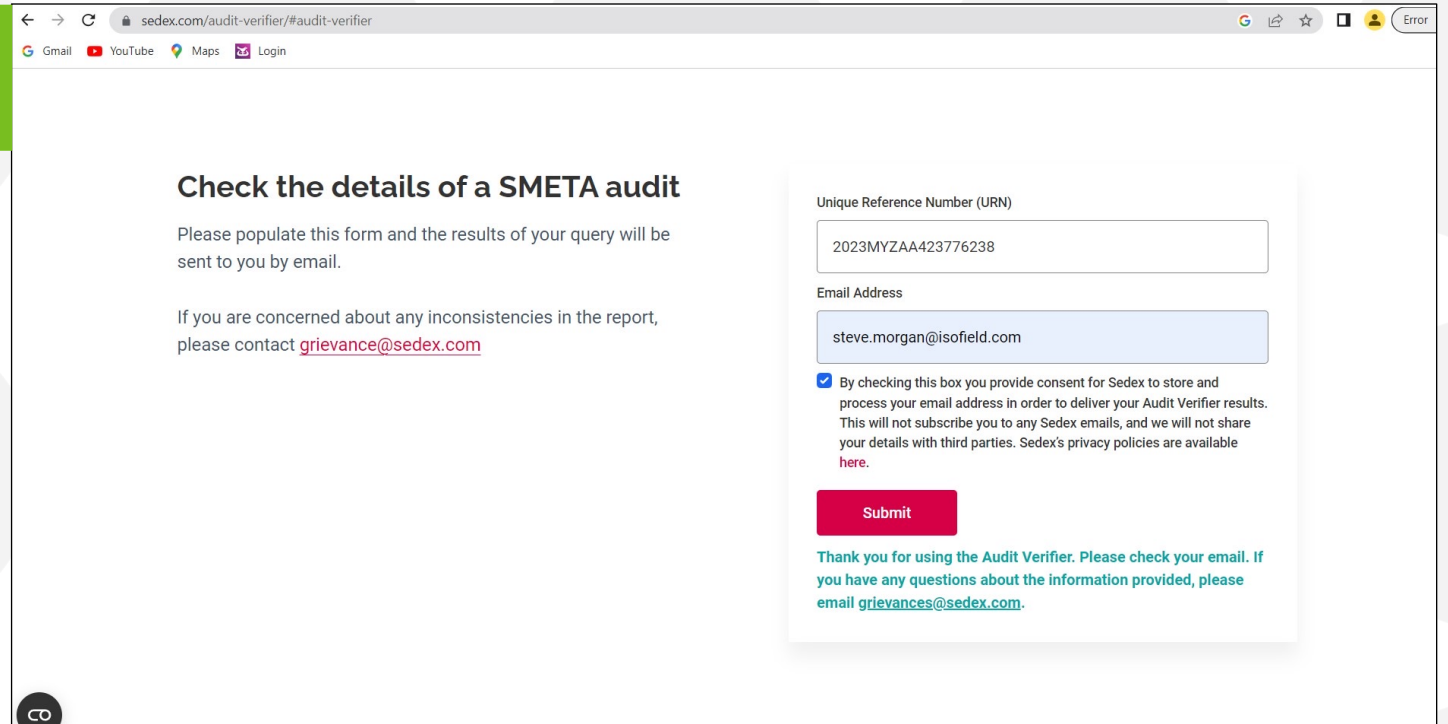
1



The screenshot shows a web browser window at the URL `sedex.com/audit-verifier/`. The page features the Sedex logo and a navigation menu with items: Why Sedex, Solutions, Become a member, Knowledge hub, and About. There are also links for a UK flag, Login, and a red Contact us button. The breadcrumb trail is `Home > Audit Verifier`. The main heading is **Audit Verifier**. The text below reads: "Our easy to use tool allows any stakeholder of a SMETA audit to verify it's details." and "Please populate the required fields below to get started. Results of your query will be sent to you by email." A note states: "Note: Audit Verifier is currently not functional for audits initiated in the new platform. This functionality will be restored during 2023". At the bottom, there are two buttons: a red "Check audit" button and a white "View auditors" button. A small circular icon with the number 2 is visible in the bottom left corner of the browser window.

Check & Verify Audit Online

2



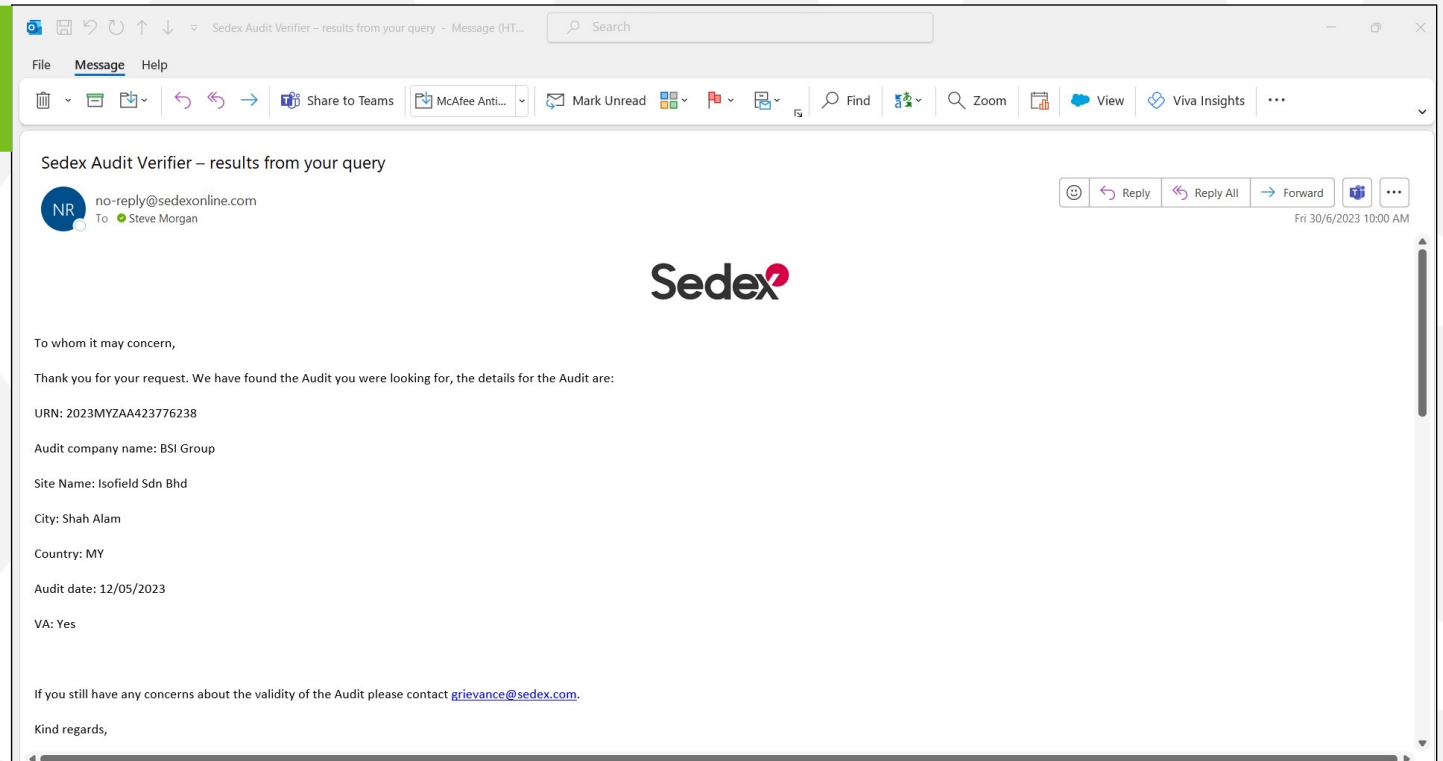
The screenshot shows a web browser window with the URL `sedex.com/audit-verifier/#audit-verifier`. The page title is "Check the details of a SMETA audit". The form contains the following fields and text:

- Unique Reference Number (URN)**: A text input field containing the value `2023MYZAA423776238`.
- Email Address**: A text input field containing the value `steve.morgan@isofield.com`.
- By checking this box you provide consent for Sedex to store and process your email address in order to deliver your Audit Verifier results. This will not subscribe you to any Sedex emails, and we will not share your details with third parties. Sedex's privacy policies are available [here](#).
- Submit**: A red button.
- Thank you for using the Audit Verifier. Please check your email. If you have any questions about the information provided, please email grievances@sedex.com.

The browser's address bar shows navigation icons for Gmail, YouTube, Maps, and Login. The bottom left corner of the browser window has a small circular icon with the number 2.

Check & Verify Audit Online

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Screenshot of an email interface showing the results of a Sedex Audit Verifier query. The email is titled "Sedex Audit Verifier – results from your query" and is from "no-reply@sedexonline.com" to "Steve Morgan". The email content includes the Sedex logo and the following information:

To whom it may concern,

Thank you for your request. We have found the Audit you were looking for, the details for the Audit are:

URN: 2023MYZAA423776238

Audit company name: BSI Group

Site Name: Isofield Sdn Bhd

City: Shah Alam

Country: MY

Audit date: 12/05/2023

VA: Yes

If you still have any concerns about the validity of the Audit please contact grievance@sedex.com.

Kind regards,

What is Annex 1

- Provide guidance for the manufacture of sterile products.
 - Notably – states principles can be applied to non-sterile products such as certain liquids,
 - creams,
 - ointments and
 - low bioburden biological intermediates,
 - where the control and reduction of microbial, particulate and endotoxin/pyrogen contamination is considered important.
- Into operation:
 - 25 August 2023
 - 25 August 2024 : for point 8.123 (lyophilizers & Sterilisation frequency)

What is Annex 1

Principle 2.1

The manufacture of sterile products is subject to special requirements in order to minimize risks of microbial, particulate and endotoxin/pyrogen contamination.

Particulate and endotoxin/pyrogen contamination. Must be important – mentioned 19 times!

Don't worry – **we are only talking about Personnel & Gowning!**

Annex 1 – Personnel

- **7.1** Suitably Trained & qualified people only in A/B
- **7.2** Minimum number of personnel required should be present in CR
- **7.3** All personnel should receive regular training, gowning qualification
- **7.4** The personnel accessing grade A/B areas should be trained for aseptic gowning and aseptic
- **7.5** Unqualified personnel not to enter A or B in operation. If needed documented procedure required
- **7.6** Need systems in place for the disqualification of personnel from working in or access to CR
- **7.7** High standards of personal hygiene and cleanliness are essential
- **7.8** Personnel who have been engaged in the processing of human or animal tissue materials
- **7.9** No non-essential items allowed (watches, make-up, jewelry, mobile phones etc.)
- **7.10** Cleanroom gowning and hand washing should follow a written procedure
- **7.11** The clothing and its quality should be appropriate for the process and the grade
- **7.12** Clothing should be chosen to limit shedding due to operators' movement

Annex 1 – Personnel

- Grade C/D
- Grade C: Hair, beards and moustaches should be covered. A single or two-piece trouser suit gathered at the wrists and with high neck and appropriately disinfected shoes or overshoes should be worn. They should minimize the shedding of fibers and particles. iii.
- Grade D: Hair, beards and moustaches should be covered. A general protective suit and appropriately disinfected shoes or overshoes should be worn. Appropriate measures should be taken to avoid any ingress of contaminants from outside the clean area. iv.
- Additional gowning including gloves and facemask may be required in grade C and D areas when performing activities considered to be a contamination risk as defined by the CCS

Annex 1 – Personnel

- Grade B (Inc access / interventions to Grade A)
- Appropriate garments that are dedicated for use under a sterilized suit
- Sterilized, non-powdered, rubber or plastic gloves worn while donning the sterilized garments
- Sterile headgear should enclose all hair (including facial hair)
- A sterile facemask and sterile eye coverings should be worn to cover and enclose all facial skin
- Appropriate sterilized footwear (e.g. over-boots) should be worn.
- Garment sleeves should be tucked into a second pair of sterile gloves
- Garments packed and folded to allow operators to don the gown without contacting the outer surface

Annex 1 – Personnel

- **7.11** The clothing and its quality should be appropriate for the process and the grade of the working area. It should be worn in such a way as to protect the product from contamination.

When the type of clothing chosen needs to provide the operator protection from the product, it should not compromise the protection of the product from contamination

Annex 1 - Personnel

- **7.4** The personnel accessing grade A and B areas should be trained for aseptic gowning and aseptic behaviours.
- Compliance with aseptic gowning procedures should be confirmed by assessment and periodic reassessment at least annually, and should involve both visual and microbial assessment (using monitoring locations such as gloved fingers, forearms, chest and hood (facemask / forehead)).

“

ANNEX 1 SECTION 8.9
Precautions to minimize microbial, pyrogen & particulate contamination should be taken

LONGER

ISOFIELD ECLIPSE
The long (400mm) length, low endotoxin, sterile nitrile Eclipse with arm-lock technology ensures no skin exposure at the wrist area.

”

ANNEX 1 SECTION 7.14.i
A sterile face mask should be worn to cover & enclose all facial skin

WIDER

ISOFIELD EXA 230 & ISOFIELD TERA 230
The widest validated sterile facemasks on the market (230mm). Our masks with tie & loop options ensure full-face coverage whilst offering excellent BFE & PFE.

“

ANNEX 1 SECTION 7.14.i
Sterile eye coverings (e.g. goggles) should be worn to cover & enclose all facial skin & prevent the shedding of droplets & particulates

CLEARER

ISOFIELD ISOCLAVE IV
With up to 35 autoclave cycles for the lens & 40 cycles for the housing, our Isoclave IV has indirect ventilation ensuring excellent airflow & a clear view whilst preventing the shedding of particles & droplets.