



MANUFACTURER

INFORMED MANUFACTURER

INTRODUCING THE NEXT STEP IN QUALITY ASSURANCE

PAUL KLINGER

**HEAD OF GLOBAL BUSINESS
DEVELOPMENT**





SESSION OVERVIEW

PROGRAM BACKGROUND

KEY ELEMENTS

BENEFITS

CERTIFICATION PROCESS

GLOBAL STANDARD

AUDIT CATEGORY

PRICING

REWARDS

MARKETING SUPPORT



WE TEST. YOU TRUST.

Quality assurance certification programmes for the sports nutrition industry backed by 60 years of anti-doping and scientific expertise.

- Finished Product Certification
- Protein Level Verification
- Manufacturing Site Certification
- Raw Material/Ingredient Certification

Consumer-Focused Programmes



SPORT

Every Lot Pre-Release Tested
+ Retail Blind Sample Testing



CHOICE

Retail Monitoring Programmes
Monthly Blind Sample Testing



PROTEIN

B2B-Focused Programmes



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Manufacturer Monitoring
for Banned Substances



INGREDIENT

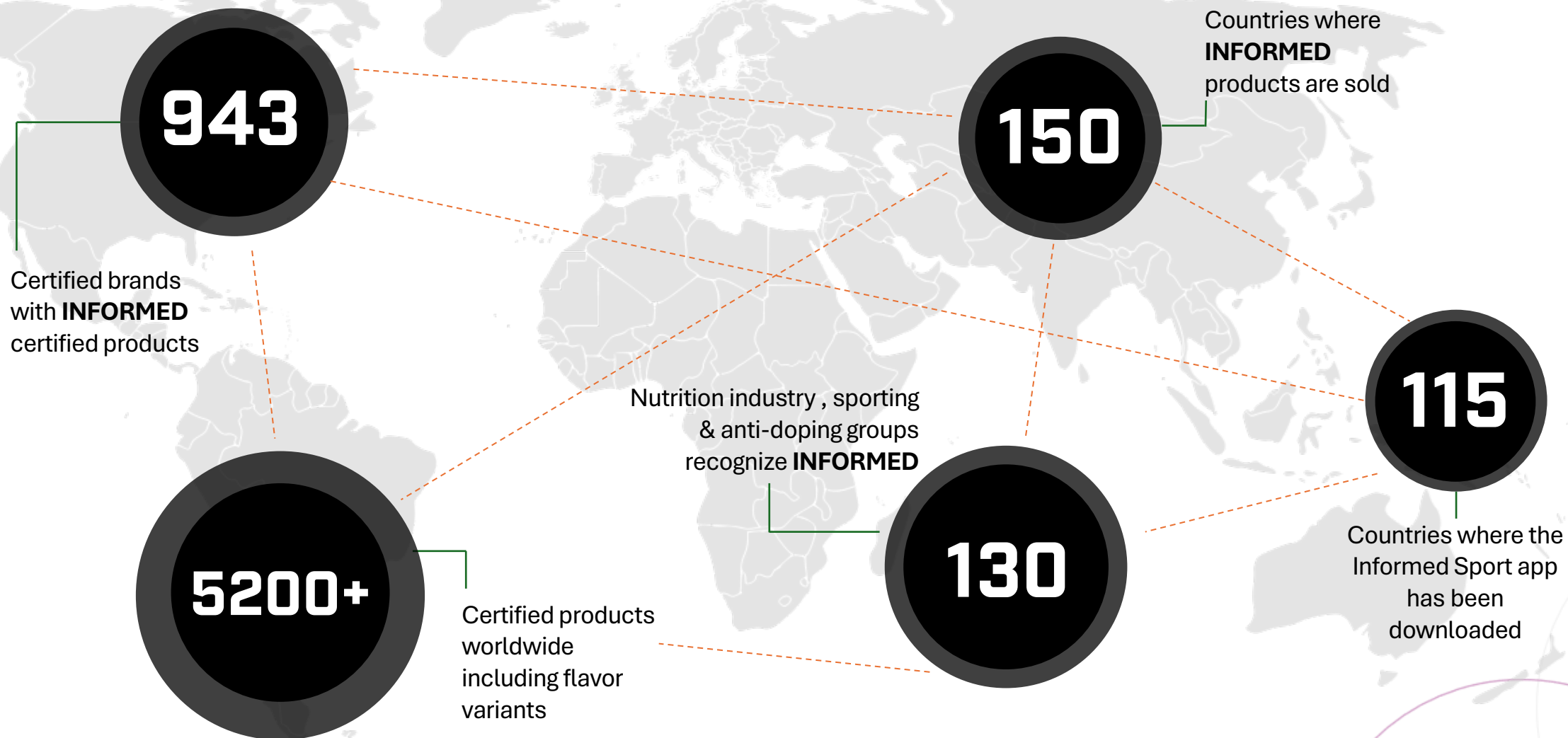
Ingredient Monitoring Testing
For Banned Substances



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GLOBAL FOOTPRINT

TOTAL SAMPLES TESTED: 229,802



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THE SPORTING LANDSCAPE

PROHIBITED SUBSTANCE VIOLATIONS IN THE NEWS



James Comben

There has been a huge amount of learning for me through this process. I would really stress to all athletes that extreme caution needs to be taken even with innocent looking products...regrettably naivety or lack of awareness is no defence in these situations... I feel gutted that I have not been around at the club for the second half of the season and wish the boys the best of luck for the last few games"

Methylhexanamine



ASAFA POWELL

Jamaican Sprinter

"I want to be clear in saying to my family, friends and, most of all, my fans worldwide that I have never knowingly or willfully taken any supplements or substances that break any rules."

Oxilofrine



DEXTER LAWRENCE

Clemson Tigers

"We get tested regularly and we know not to do anything stupid or selfish like that," he said (via ESPN). "That's why this is such a shock." "I didn't want my last game to be Pitt [in the ACC championship]," he added. "I wanted my last game to be the closer. That's what we'd been fighting for each game. I wouldn't wish this on anybody."

Ostarine



RHYS WILLIAMS

British Hurdler

"I am utterly devastated about the news of this anti-doping rule violation, which has come as a great shock to me. From the outset, I would strongly like to state that I have not knowingly taken any banned substance."

Anabolic steroids



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THREATS

MOST COMMONLY FOUND PROHIBITED SUBSTANCES [US]

- DHEA (Most Common)
- 5(6)-androstene-3 β ,17 β -diol
- 1,4-androstadiene-3,17-dione
- Ephedrine/Norpseudoephedrine
- Methamphetamine
- DMBA (1,3-Dimethylbutylamine)
- Amphetamine “like” compounds
- Oxilofrine
- Ostarine
- Higenamine
- Bupropion (cross contaminated raw material)
- Sildenafil (male enhancement)



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LEVELS OF CONTAMINATION

- Part Per Billion Level (ppb)
e.g. 10 nanogram per gram of product
- mg/ml = part per thousand
- $\mu\text{g/ml}$ = parts per million
- ng/ml = parts per billion

1 US Dollar bill = 1g

- $1/1000 = 1\text{mg}$
- $1/1,000,000 = 1\mu\text{g}$
- $1/1,000,000,000 = 1\text{ng}$

1 NG/ML = ONE SUGAR CUBE IN AN OLYMPIC POOL



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SOURCES OF CONTAMINATION

RAW MATERIALS



Contamination at source of manufacture

Imported raw materials from high-risk countries of origin

Botanical products – natural steroids or stimulants

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Poor cleaning processes and cross-contamination

Improper handling of high-risk raw materials

Handling of banned substances in manufacturing facilities



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SUPPLEMENT CERTIFICATION PROCESS



Quality Systems Review Process

- Product/ingredient evaluation
- Raw material evaluation at each production/packing site
- Raw material supplier assessment procedures
- SOP review for critical control points in all production/packing areas including cleaning, ingredient handling, employee hygiene
- Verification for label verification testing, identity and contaminant testing
- GMP verification
- Pre-certification sample testing



CHOICE



SPORT

1 in 10,000 Informed Choice/Informed Sport certified products had a positive screening indication.



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TAKE THE NEXT STEP IN QUALITY ASSURANCE



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Minimise Risk

Protect your business and brand by lowering the likelihood of banned substance contamination

Convey Commitment

Clearly communicate best-practice quality controls to new and existing customers

Build Brand Confidence

Differentiate from other manufacturers to nurture confidence when developing new relationships



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KEY ELEMENTS OF INFORMED MANUFACTURER



Desk-based **certification audit** interrogating production and quality processes in detail



Onsite certification assessment including site inspection and testing of swab samples for substances prohibited in sport



Annual **recertification** process including desk-based manufacturing audit and swab testing



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CERTIFICATION PROCESS

STAGE ONE

Desk-Based Audit



Desk-based audit
Onsite inspection

STAGE TWO

Site Visit and Swab
Sample Testing



Site collects and returns
swabs
Swab analysis by LGC

STAGE THREE

Certification Completion,
Logo Use & Web Listing



Report issued
Certificate issued
Logo use licensed
Brand training

STAGE FOUR

Recertification Audit and
Swab Testing



Desk-based audit
Swab collection, return
and analysis
Certificate and report
re-issued



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CERTIFICATION PROCESS

GLOBAL STANDARD & DESK-BASED AUDIT

Clear, robust and transparent standard

Covers food safety, quality and banned substance risk management

Audit requires document references for all points and evidence for all points over a 3-yearly cycle

Management Commitment & Responsibility

- Management and Organisational Structure
- Management Review
- Prohibited Substances
- Documentation Control and Record Keeping

Food Safety & Quality Management System

- Food Safety Policy
- Risk Assessment & Preventative Actions
- Personnel & Training

Traceability & Product Control

- Traceability System & Procedures
- Product Quarantine & Release
- Product Recall Procedures
- Internal Audits
- Non-conformities & Corrective Actions
- Complaint Handling

Operational Control & Production

- Operational Control
- Purchasing & Supplier Management
- Raw Materials
- Product Specs, Labelling & Packaging
- Receipt & Storage of Goods
- Plant Layout & Process Flows
- Construction & Maintenance
- Cleaning & Disinfection
- Waste Management
- Pest Control



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CERTIFICATION COSTS

BASED ON SIZE, NUMBER OF EMPLOYEES, NUMBER OF PRODUCT FORMULATIONS

- Costs are based on a calculation information provided on the Informed Manufacturer Information Form (IMIF)
- The Final Audit Category takes account of any unique site characteristics to ensure an appropriate audit and swab testing schedule.
- Flexibility is allowed for very large or very small sites that may not fit into the model shown
- Sites will be informed of the Final Audit Category prior to each assessment



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CERTIFICATION COSTS

BASED ON SIZE, NUMBER OF EMPLOYEES, NUMBER OF PRODUCT FORMULATIONS

Scoring Factors					
Factor Value	1 Point	2 Points	3 Points	4 Points	5 Points
Square footage	Under 51K	51-100K	101-200K	201-400K	400K plus
No of employees	1 - 19	20 - 69	70 - 149	150 - 349	350 plus
Product formulations	1	2	3	4+	

Site Score	Base Audit Category
1 - 4	A
5 - 7	B
8 - 10	C
11 -12	D
13 - 14	E



CERTIFICATION COSTS

SIMPLE PRICING, CLEAR EXPECTATIONS

	Category A	Category B	Category C	Category D	Category E
Swabs	10	15	20	25	30
Cost (€)	€4,240	€5,170	€5,650	€6,470	€7,290

Certification and annual recertification costs include:

- Desk-based audit, onsite inspection*, swab testing & license to use Informed Manufacturer logo

Sites unable to provide evidence of working to an accepted quality standard (e.g. GFSI-recognized, GMP, etc.) require an enhanced audit with an additional fee of 570€ (only at certification)

Remote assessments have proven to be an effective way to conduct desk-based audits to enable communication with the INFORMED team once all required information is available. Auditors may request to visit the site in the rare instance of major non-conformities

Onsite recertification visits are an option, please contact your LGC representative for availability and costs

** Onsite inspection typically only required at certification. Travel & accommodation for the onsite inspection at certification is charged separately.*



CERTIFICATION COSTS

SIMPLE PRICING, CLEAR EXPECTATIONS

	Category A	Category B	Category C	Category D	Category E
Swabs	10	15	20	25	30
Cost (£)	£3,750	£4,575	£5,000	£5,725	£6,450

Certification and annual recertification costs include:

- Desk-based audit, onsite inspection*, swab testing & license to use Informed Manufacturer logo

Sites unable to provide evidence of working to an accepted quality standard (e.g. GFSI-recognized, GMP, etc.) require an enhanced audit with an additional fee of £500 (only at certification)

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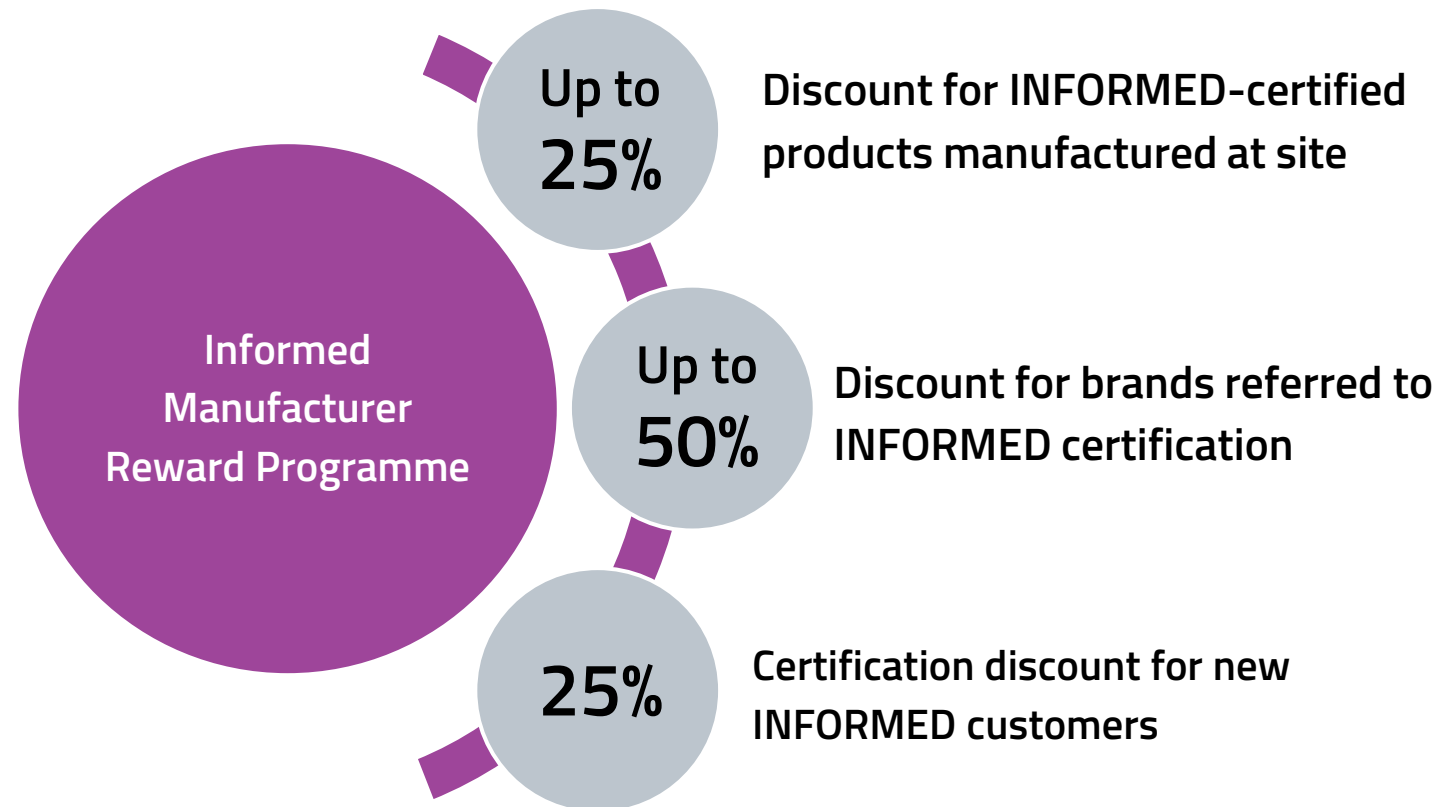


REWARDS PROGRAMME



INFORMED REWARDS

IMPROVE RETURN ON CERTIFICATION INVESTMENT AND INCREASE INTEGRITY AND TRUST IN THE SUPPLY CHAIN



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INFORMED REWARDS

IMPROVE RETURN ON CERTIFICATION INVESTMENT AND INCREASE INTEGRITY AND TRUST IN THE SUPPLY CHAIN

Certification

Sites receive discount on certification fees according to the number of INFORMED-certified products manufactured (minimum 5)*

Number of Products	5 - 14	15 -24	25 – 39	40+
Discount	5%	10%	15%	25%

Brand Referral Discount Initial

Earn 5% off recertification fees for each brand referred that is new to INFORMED and successfully earns a product certification (Informed Sport, Informed Choice, Informed Protein, Informed Ingredient), to maximum of 50%*

Downstream Discount (for Your Customers)

Support new business development with the ability to secure your customers a 25% discount off the list price for certifying product(s) with Informed Sport, Informed Choice, Informed Protein or Informed Ingredient if they are new to INFORMED

**Total maximum discount is 50%, discounts are calculated and applied automatically and will be itemized on certification invoices.*



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INFORMED REWARDS

EXAMPLE DISCOUNT SCENARIOS

Line Item	Factor	Value
Certification Fee	Category A	£3750.00
Certified Products Manufactured	8 (-5%)	-£187.50
Number of Brands Referred	2 (x 5%=10%)	-£375.00
Invoice Total		£3185.50

Line Item	Factor	Value
Certification Fee	Category C	£5000.00
Certified Products Manufactured	22 (-10%)	-£500.50
Number of Brands Referred	6 (x 5%=30%)	-£1500.00
Invoice Total		£3000.50

Line Item	Factor	Value
Certification Fee	Category E	£6450.00
Certified Products Manufactured	28 (-15%)	-£967.50
Number of Brands Referred	7 (x 5%=35%)	-£2257.50
Invoice Total		£3225.00



MARKETING SUPPORT



INFORMED MARKETING SUPPORT



Promoting Your Certification

Dedicated webpage profile
(photos, contact and manufacturing capabilities)

Logo usage training

Social marketing collaboration

Website content template



Rewards Programme

Educational collateral and slideware

Email and website content templates

Referral tools and dedicated URL



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THANK YOU!

Q&A

Please contact your LGC representative
with any questions regarding
certification or rewards program.



CERTIFICATION COSTS

SIMPLE PRICING, CLEAR EXPECTATIONS

	Category A	Category B	Category C	Category D	Category E
Swabs	10	15	20	25	30
Cost (US\$)	\$4,760	\$5,810	\$6,350	\$7,270	\$8,190

Certification and annual recertification costs include:

- Desk-based audit, onsite inspection*, swab testing & license to use Informed Manufacturer logo

Sites unable to provide evidence of working to an accepted quality standard (e.g. GFSI-recognized, GMP, etc.) require an enhanced audit with an additional fee of US\$630 (only at certification)

Remote assessments have proven to be an effective way to conduct desk-based audits to enable communication with the INFORMED team once all required information is available. Auditors may request to visit the site in the rare instance of major non-conformities

Onsite recertification visits are an option, please contact your LGC representative for availability and costs

** Onsite inspection typically only required at certification. Travel & accommodation for the onsite inspection at certification is charged separately.*

