CANNABIS COMPLIANCE BUREAU

NICO KRIEK – QA & REGULATORY

TABLE OF CONTENTS

Cannabis Compliance Bureau – RSR Labs

Our Mission

Setting the standards on pharmaceutical practices and Agriculture developments on Cannabis Cultivation making products produced over Africa acceptable on international standards.

CCB TEAM

CCB REPRESENTATIVES

Nico Kriek
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Johann Slabber

Christiaan Viviers

Mario Du Plessis

Rosemary Kietzmann

Keagan Du Plessis

Thomas Walker

Jodi-Rae Chappen

Sean Campher

Tayla Clemo

Danie Gerber

Dr. Giba Ntombikayise

CANNABIS COMPLIANCE BUREAU

The role of CCB and the services they offer

CANNABIS COMPLIANCE BUREAU

Why the CANNABIS COMPLIANCE BUREAU

The Cannabis Compliance Bureau is a regulatory compliance company that consists of a whole team of experts in different divisions that has been involved in the pharmacy and compliance industry. CCB ensure that Quality Control and Quality Assurance is always adhered to , this includes but is not limited to:

1. Good Document Practice are always maintained
2. Legal Matters Compliance are met
3. Cannabis Cultivation is regulated and procedurally detailed for all to understand
4. Security is of good quality and compliant with requirements and safety
5. Facility and Product Handling that ensures all Housekeeping Standards are always met and the product is handled correctly throughout the process.
6. Good Manufacturing Practice – to ensure that all tests and product analysis are up to standard

CANNABIS COMPLIANCE BUREAU

Why the CANNABIS COMPLIANCE BUREAU

The Cannabis Compliance Bureau offers training and induction on the inspection process to all workers/farmers/ and contractors, ensuring that they understand the process and take the necessary responsibility to make use of these good standards to ensure quality, safety and compliance with regulations are met.

We also do PIA (Pre-Inspection Audits) to ensure that the facility, staff and systems are compliant with the requirements before SAHPRA comes to do the site inspections.

We do Validations to ensure all systems, procedures and equipment is functional, compliant, maintained and detailed in the Quality Management System in the Standard Operating Procedures.

CCB has a Project Manager team that can built or construct these facilities and supply the equipment necessary for the projects.

CANNABIS COMPLIANCE BUREAU

Why the CANNABIS COMPLIANCE BUREAU

We offer continuous relationships with all customers to maintain the systems, educate and train them to assist in the process forward.

CCB being one of the first and only companies yet again that offers the full turnkey operation. From the pharmaceutical and regulatory compliance to validations and development of the actual facilities, and the management of the project and the CULTIVATION.

THE CULTIVATION AND ONGOING SUPPORT THAT CCB OFFERS ARE THE MOST IMPORTANT ASPECT FOR THE FINAL PRODUCT AS WE MAKE SURE THAT WE ARE INVOLVED IN HELPING CUSTOMERS TO GROW THE FINAL PRODUCT TO EXPORT THEREOF THROUGH OUR INTERNTIONAL PARTNERS.

CANNABIS COMPLIANCE BUREAU

Why the CANNABIS COMPLIANCE BUREAU

Above that CCB also offers the management of these projects and provide the offtake agreements/buyers for all the product.

CCB has set the standard in South Africa by being the first to combine Good Practices in addition to Good Agriculture Practice

We have over 80 committed development projects in South Africa

We are registered in Lesotho

We successfully submitted 12 submissions

The first license issued in South Africa is also a customer of CCB

CANNABIS COMPLINCE BUREAU
CONCLUSION OF CCB

CCB will form a footprint in Southern Africa & Africa and be industry leaders. We are growing a cannabis industry that is developed from south African resources instead of overseas investors.

We are currently building our own facilities and we want to create a central supply and process hub where all training and product processing will take place before it is exported.

Cannabis in Conclusion

There is absolutely no doubt that Cannabis has been proven to have medicinal benefits. Cannabis is classified as a high valued crop and due to the benefits and value it can add, we want to grow a cannabis industry that is developed from south African resources instead of overseas investors.

THE MEDICINES CONTROL COUNCIL (SAHPRA)

STANDARDS AND PROCESSES

In 2017 the Medicines Control Council now know as the South African Health Products Regulatory Authority published the first application process available to Cultivate and export Medicinal Cannabis under the provisions of The Medicines and Related Substances Act 101 of 1965, in terms of section 22C and 22D to be read in conjunction with regulation 23 and 24 of the Act. In order to obtain such a license, you need to comply with the standards set in the document published in 2017 by SAHPRA in V2.2 and ensure that all requirements are met.

Cannabis is classified as a schedule 7 Drug under section 21, this means that a doctor may import a small quantity for a patient to use due to other medicines not being effective. The doctor needs to motivate the reason why and every step of the process is recorded.

Under the License Cannabis is classified as a schedule six for THC (THC is the cannabis ingredient that is psychoactive) and CBD a schedule 4 that is non psychoactive.

In May 2019 SAHPRA published the standard stating that 20mg of CBD may be used legally, however South Africa does not have a finished registered product and due to this it is still illegal. The aim of this publishment was to make it clear for the SAPS on when it is now legal or illegal when someone is caught with the possession of cannabis and or use thereof.

THE MEDICINES CONTROL COUNCIL (SAHPRA)

STANDARDS AND PROCESSES

To provide an example of a finished registered product and why it is so important can be done in the following way:

When you are sick, and you see the doctor and he prescribes antibiotics to kill the infection you must go to the pharmacy to get the antibiotic the doctor prescribed.

When you get there, they will ask you if you are allergic to penicillin should it be a Beta lactam chemical class antibiotic for example.

The Pharmacist then explains how you should take the medicine and how it will work and what the common side effects are.

The medicine then comes with a package insert with all the information of the medicine and how it works.

This Antibiotic that you received has been tested through laboratories, it has been manufactured in sterile and clean environments and everything that is in the medicine has been proven. It also has a stability factor which means that the next customer will get the same product that will work the same way and provide the same results.

In South Africa people are selling Cannabis illegally. The grow it at their homes and do their own extractions. They then sell it on the market stating the various uses thereof, however there is no control in this procedures, at then end of the day the person buying the product has no idea what he/she is taking and how it will work, what the side effects are etc.

THE MEDICINES CONTROL COUNCIL (SAHPRA)

STANDARDS AND PROCESSES

Thus it needs to be regulated in controlled environments and we need to abide by the ethical standards and quality measures to ensure quality control and quality assurance for end user consumption.

Not only is the legal and pharmaceutical way under the license more beneficial as it offers better prices due to quality, it will also benefit the communities and uplift the quality of lives.

The Medicines Control Council then further requires that you should have the following in place before a license is issued. In South Africa everything needs to be built first so that when they conduct the inspection, they can see that you do have all measures in place to be able to handle such a high scheduled product.

The Cultivation area (Tunnel, Greenhouse, Multispan etc.)
The Processing Facility to handle the product after it was grown up until the packaging in final form to be exported
Quality Management System to manage all the pharmaceutical processes.
Site Master File which is a site-specific document detailing everything on your operation
A business plan to ensure that your process will be viable and is well planned
The offtake agreement (The buyer of the product)
Etc.

THE MEDICINES CONTROL COUNCIL (SAHPRA)

The Stages and Inspection Process

1

Once the application is submitted the inspection will be done 4 months after submission

2

The first round of inspection is now done and if any deviations is found a second round will be done

3

2nd round of inspection is now done and if the deviations found on 1st round was not fixed then a third round will have to be done

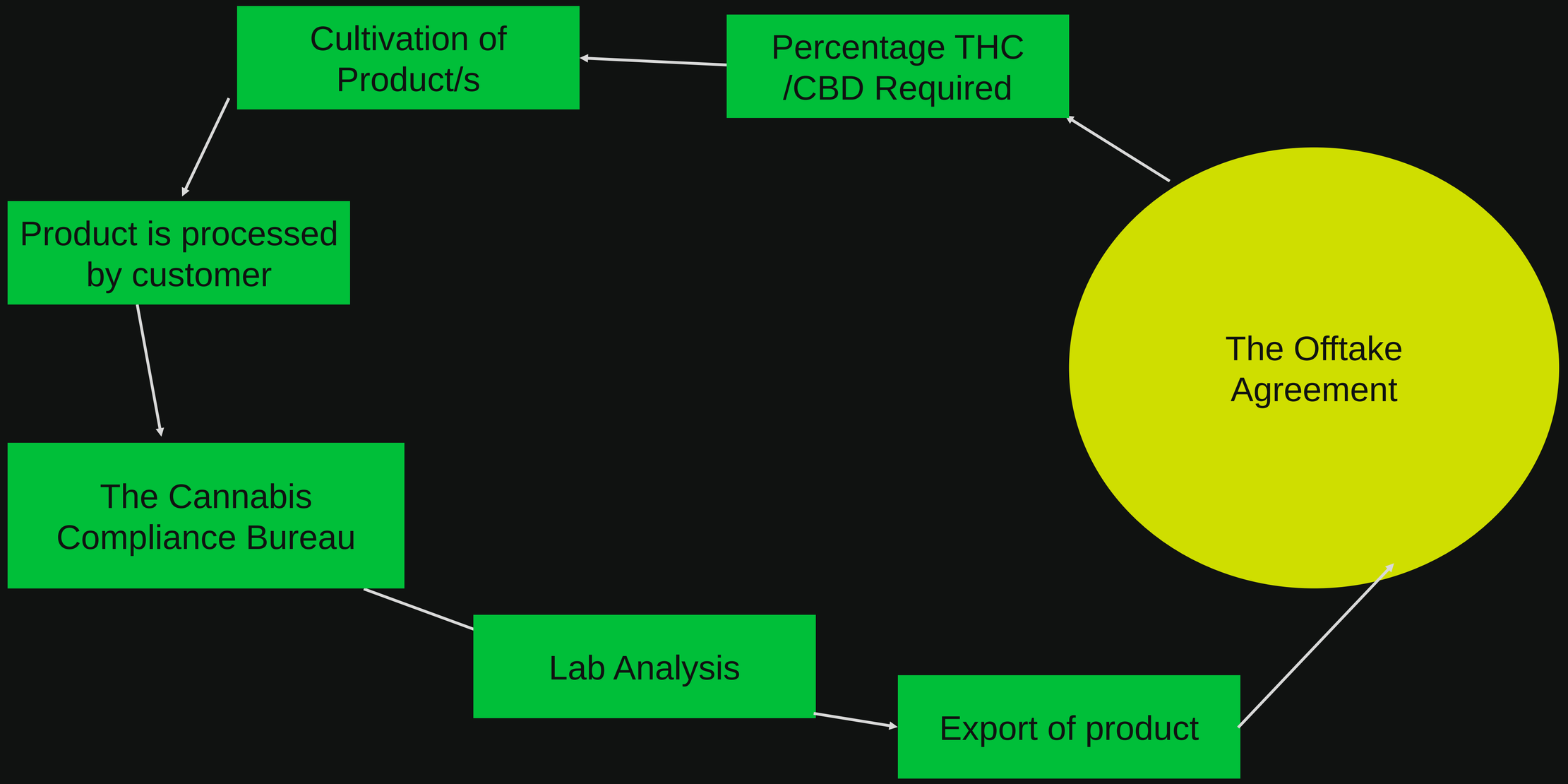
4

3rd round of inspection is now done and if nothing has been done still then a new application is submitted and the process is completed.

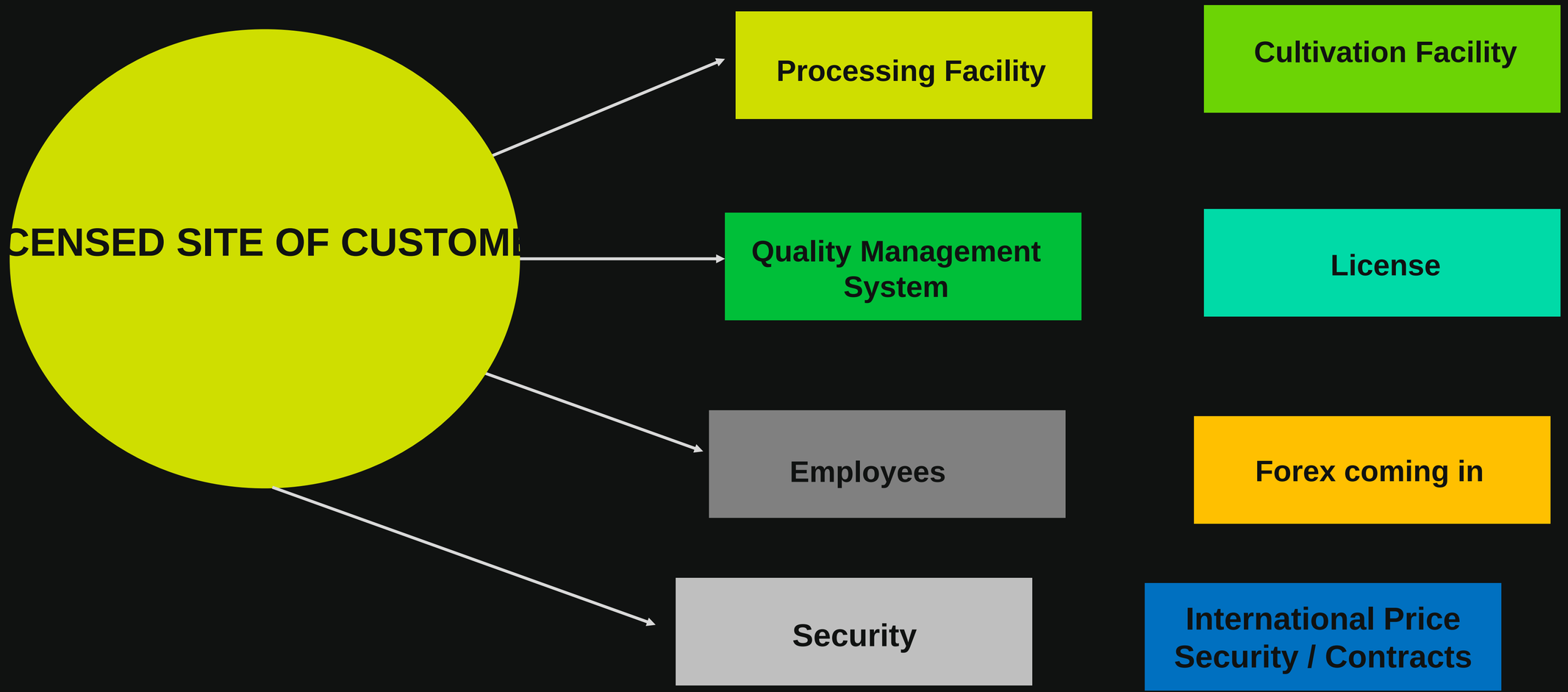
5

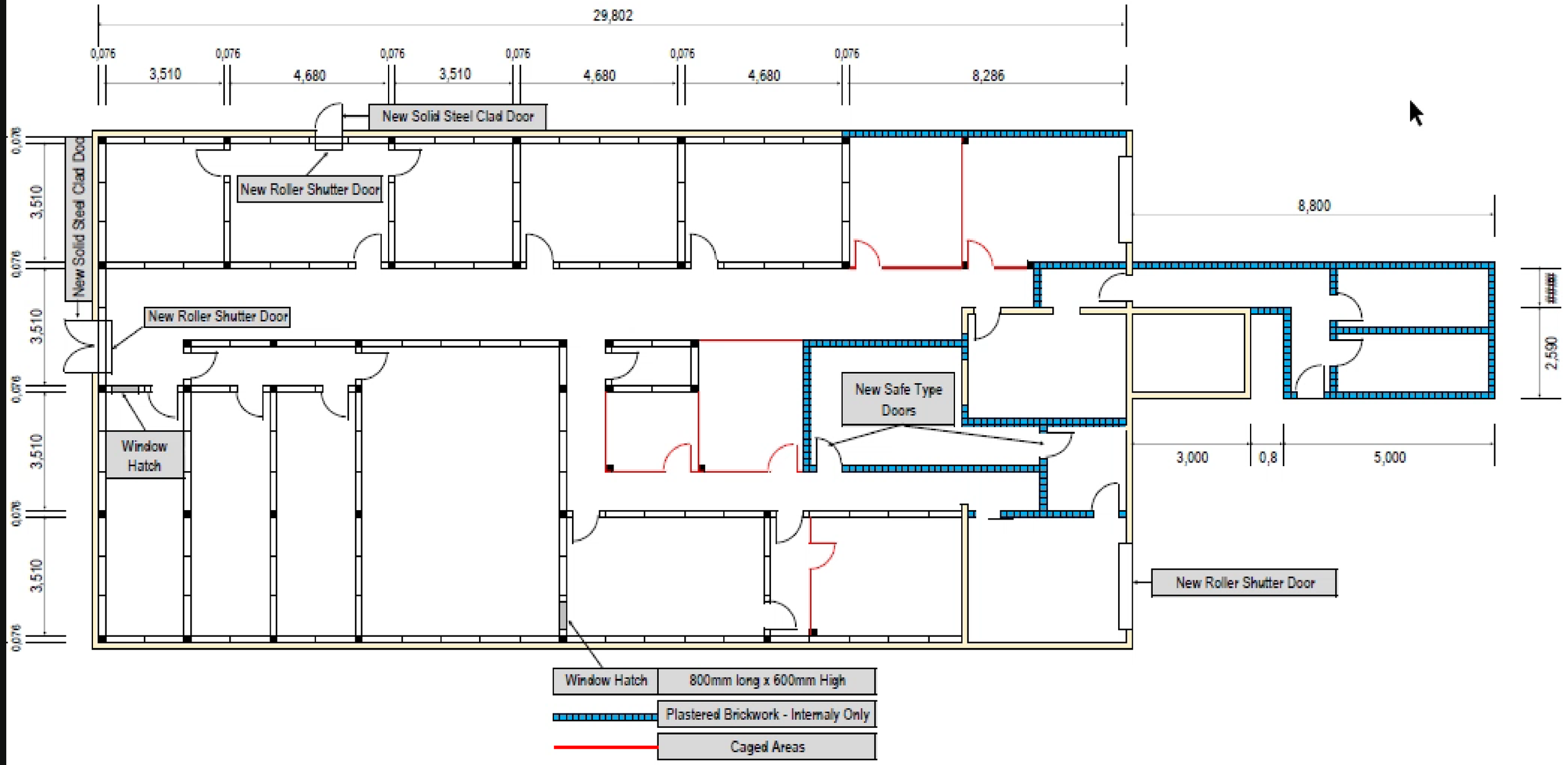
If everything was done the license is issued and you can start with the process immediately. The license is issued on the site and cannot be used on another farm

Summary of Supply Process



Licensed Site Basis




29,802
0,076
3,510
4,680
3,510
4,680
4,680
8,286
New Solid Steel Clad Door
New Roller Shutter Door
New Solid Steel Clad Door
New Roller Shutter Door
8,800
2,590
New Safe Type Doors
Window Hatch
3,000
0,8
5,000
New Roller Shutter Door
Window Hatch
800mm long x 600mm High
Plastered Brickwork - Internaly Only
Caged Areas

ANY QUESTIONS?


THANK YOU!

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