



SIGNATURES AND AUTHENTICATION FOR EVERYONE

***SAFE-BioPharma Operating Policies
Participant Rights & Responsibilities***

8 June 2009

Version 2.3

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Revision	Date	Revised By	Summary of Changes/Comments
1.1	July 2004	G. Tallent	Conformance changes from LWG and to incorporate Dispute Resolution procedures
1.2	Oct 2004	MBR	LWG rules clarifications

Revision	Date	Revised By	Summary of Changes/Comments
1.3	Mar 2005	Rich Furr	<p>Added disclaimers, Sec 4.1.2, Membership categories added and defined, Sec 5.1.1, SAFE-BioPharma transaction defined, Sec 5.1.2.3 added principles related to digital signature binding, Sec 5.2.3.2 Added government Organization responsibilities for Termination, Obligation to Destroy and Notice dealing with confidential information, Sec 5.3.2 Added clarification that Policy does not preclude right of Government agency to audit, Sec 5.5.1.2 added wording to support alternate Government Organization Membership agreement, 5.5.2.1 added wording to limit designated party rights under SAFE-BioPharma, Sec 5.5.2.1.c.i inserted language specifying credentialing of independent investigators., Sec 5.5.2.1.e added phrase to limit responsibility for omission to the extent permitted by law, Sec 5.6.2.1 limited policy enforcement for Government members to requirements of law, , Sec 5.6.4 limited enforcement for Government Members, Sec 5.7.1 limited to the extent permitted by law, Sec 5.7.3, Liability provisions clarified, other minor changes, change SAFE-BioPharma, LLC to SAFE-BioPharma, throughout. Sec 5.7.7.2.iv Sec specifying liability for the I&A of independent investigators, Sec 5.7.10 Added section for government Organizations liability requirements.</p>
2.0	15 Sep 05	R. Furr	Minor edits for Version 2.0
2.1	16 Feb 2006	R. Furr	Update for SAFE-BioPharma logo change. Revised fee notification requirement (sec 4.1) to 60 days.

Revision	Date	Revised By	Summary of Changes/Comments
2.2	11 Oct 2007	R. Furr	Update to include SAFE-BioPharma Association Member classification. Section 2.1.1 - Added wording to support system and facility authentication; Section 2.1.2 - clarified the position of affiliates of Member companies; Section 2.1.2.1 – added provision to support Associate Membership for organizations that are directed to use the SAFE-BioPharma certificate for authentication to Government managed systems; Section 2.1.3 – added clarification of the role of an issuer as a CA; Section 2.1.4 – added pertinent SAFE-BioPharma Standard Documents to applicable responsibilities of Agents and Third Parties; Section 3.1 – added disclaimer regarding transactions using certificates from cross certified PKIs that are not part of the closed SAFE-BioPharma contract structure, e.g., the FBCA; Section 3.1.1 – added requirement that digital signature be created using a certificate issued under provisions of the SAFE-BioPharma Standard; Section 3.2.6 – added Member to Accreditation Process to clarify; Section 3.3.1.2 added provision to cross certify with the FBCA; Section 3.4 added SAFE-BioPharma RCMS Tech Spec to requirements for Issuers; Section 3.5.1.4 – added requirement for Members to establish Trusted Agents or SAFE-BioPharma requestor roles

Revision	Date	Revised By	Summary of Changes/Comments
2.3	8 June 2009	Rich Furr, GBRWG	<p>Section 2.1.2.1. Refined definition of full member to restrict to entities actively engaged in biopharmaceutical development and manufacturing and healthcare delivery; Added category 4 for business partners of limited business transactions; Section 2.1.3 – Expanded the definition of SAFE-BioPharma Issuers to include Certification Authorities cross certified with a bridge CA that is cross certified with the SAFE-BioPharma Bridge CA. Such a CA must enter into an Issuer Agreement with SAFE-BioPharma; Section 2.1.4 Other Participants – deleted due to revision of other classes and fee structure; renumbered Section 2.1.4.1 as 2.1.4; Section 2.1.4.2 renumbered as 2.1.5 Section 3.1 – added description of signatures that maybe generated but not fall under the provisions of the SAFE-BioPharma Standard; Section 3.1.1 – refined requirement to state that the relying party must be affiliated with a SAFE-BioPharma Member for the signature to be covered as a SAFE-BioPharma transaction; Section 3.1.1 – Tables – added row for previous situation; revised throughout for logo and trademark changes; Section 3.4.2.2 – Added the SAFE-BioPharma Certificate Policy to documents binding on an issuing CA; Section 3.4.2.4 – Added the CP, End User System Technical Specification and the Central Certificate System Specification of the list of documents required for Issuers; Section 3.2.4.6 & 7 – Added CP to CA guidance documents; 3.5.1.3- clarified requirement for Members to specify only allowable Applicants for issuance of a SAFE certificate; Section 3.5.1.4 – deleted requirements for Members to delegate Registration Agents and Trusted agents since this can only be done by the CA and RA; Section 3.5.2.7 – established requirement for Members to develop an internal policy to require Subscribers to safeguard their private key.</p>

Disclaimers

General Disclaimer

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Approval Statements

Once signed by the parties indicated below, this SAFE-BioPharma Operating Policies document has been approved by the SAFE-BioPharma Policy Authority Committee and has been incorporated into the SAFE-BioPharma Standard Document Set.

SAFE-BioPharma PAA Chairperson
Gary Secrest

Date

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1. Introduction

1.1 Purpose & Scope

The purpose of this document is to:

- Provide an introduction to SAFE-BioPharma operating principles and requirements;
- Identify the SAFE-BioPharma Stakeholders; and
- Set forth their respective legal rights and obligations with respect to their participation in the SAFE-BioPharma System.

1.2 Definitions

For purposes of this SAFE-BioPharma Operating Policies document, all terms used shall have the meanings set forth in the *SAFE-BioPharma System Documentation Glossary*.

1.3 References

These Operating Policies will make reference to the SAFE-BioPharma policies, guidelines and specifications. These are general references to the body of documents that provide standards, policies, guidelines, and specifications including:

- Member Accreditation Process
- Change Management Process
- Transaction Dispute Resolution Process
- SAFE-BioPharma-Enabled Application Specification
- End-Subscriber Systems Technical Specification
- Machine Systems Technical Specification
- Registration and Certificate Management Technical Specification

- Central Systems Technical Specification
- Digital Signature Use & Verification Functional Process Guidelines
- SAFE-BioPharma e-Identity Management Functional Process Guidelines
- Policy Authority Committee Charter
- SAFE-BioPharma System Documentation Glossary.

2. SAFE-BioPharma Stakeholders

SAFE-BioPharma Stakeholders directly contribute to the success of the SAFE-BioPharma Standard in achieving the SAFE-BioPharma Standard's stated objectives, satisfying the key business requirements for SAFE-BioPharma, and sustaining the long-term viability of the SAFE-BioPharma System. SAFE-BioPharma Stakeholders directly influence the evolution of the SAFE-BioPharma System, the SAFE-BioPharma Standard Document Set, and associated SAFE-BioPharma Services. The three contractually bound classes of SAFE-BioPharma Stakeholders are: SAFE-BioPharma Association (SAFE-BioPharma), SAFE-BioPharma Members and SAFE-BioPharma Issuers.

2.1.1 SAFE-BioPharma

SAFE-BioPharma is a member-regulated, not-for-profit company that was formed by the Pharmaceutical Research and Manufacturers Association (PhRMA) to develop and maintain a standard, and as required a supporting infrastructure, for the management of digital identities and the use of digital signatures in the biopharmaceutical and healthcare industries. SAFE-BioPharma develops, maintains and enforces SAFE-BioPharma standards that are embodied in the various Policies, Guidelines and Specification documents¹ that form the basis for the operations and governance of the SAFE-BioPharma System. SAFE-BioPharma is also the legal entity that binds SAFE-BioPharma Members and SAFE-BioPharma Issuers to comply with the SAFE-BioPharma Standards by virtue of SAFE-BioPharma Members and SAFE-BioPharma Issuers contractually agreeing to the terms of these Operating Policies. SAFE-BioPharma provides a common trust bridge² among the SAFE-BioPharma Stakeholders that result in the ability to make and validate legally enforceable Digital Signatures and to operate a network of trust for authentication to systems and facilities using SAFE-BioPharma digital identities. SAFE-BioPharma facilitates compliance with regional regulations and laws on a global basis that allow Digital Signatures to be used in lieu of hand-written signatures.

SAFE-BioPharma's Board of Directors authorizes the SAFE-BioPharma Policy Approval Authority (PAA) to manage and administer these Operating Policies pursuant to provision 3.6.1.2.

¹ Cited documents are maintained in the SAFE-BioPharma SharePoint instance at the following url:
<http://sharepoint.safe-biopharma.org/SAFEBioPharma%20Standard%20Document%20Set/Forms/AllItems.aspx>

² The collection of hardware, software, policies, procedures and agreements that allow subscribers to one Public Key Infrastructure Domain to rely on digital certificates issued by other Public Key Infrastructure Domains. Often referred to as a "trust anchor".

2.1.2 SAFE-BioPharma Members

SAFE-BioPharma Members are contractually bound to adhere to the SAFE-BioPharma Standards, including the Operating Policies, for the benefit of the SAFE-BioPharma Members and their Affiliates using the SAFE-BioPharma System and obtaining SAFE-BioPharma services. For purposes of these Operating Policies, a SAFE-BioPharma Member's Affiliates shall not be considered third parties to these Operating Policies.

A SAFE-BioPharma Member's affiliates as defined in the SAFE-BioPharma System Glossary are considered bound to the SAFE-BioPharma Standard by virtue of the Member Agreement signed by the SAFE-BioPharma Member. The affiliate shall not be responsible for additional fees over and above those paid by the SAFE-BioPharma Member. The affiliate shall not however, be afforded certain rights under these policies as they apply to Board Membership and voting rights on matters considered by the Board. Affiliates may participate in the activities of SAFE-BioPharma Working Groups.

2.1.2.1 SAFE-BioPharma Member Categories

The Members of SAFE-BioPharma shall be divided into the following four categories: Full Members, Government Members, Association Member and Associate Members. These categories include the following:

1. Full Members. Entities that join SAFE-BioPharma with the intent of using SAFE-BioPharma credentials in business to business and business to regulator transactions, including ,
 - For-profit Entities engaging in, or supporting biopharmaceutical, medical device, or health care lines of business as primary participants such as biopharmaceutical research and development manufacturing, sales and marketing companies and healthcare delivery entities or organizations of such entities (e.g., health information exchanges) or as business partners, e.g., business partners, IT outsourcing contractors, clinical investigators, chemical precursor suppliers, contract research organizations, pre-clinical laboratories, supply chain partners or suppliers, payers, etc.,
 - Not for Profit/Nonprofit Entities such as university research organizations; hospitals, etc. which meet the preceding definition;
 - Other for-profit entities that may be approved by the SAFE-BioPharma Board on an individual basis,
 -
2. Government Members: Government organizations that can be considered part of the BioPharmaceutical community.
3. Association Members: organizations that meet the description of those that would otherwise be Full Members, but choose an initial limited membership with restricted rights and responsibilities as defined in the following table. This class of membership is designed to allow Association Members access to the Standard documents and certain tools, such as credentials to use in SAFE-BioPharma pre-production proofs of concept and pilots prior to committing to Full Membership. Association Members may not implement operational systems and are not covered by any of the liability or other legal protections of Full Membership. Association Member credentials are not production credentials in the sense that any digital signatures applied with these credentials are not SAFE-BioPharma transactions under the SAFE-BioPharma Standard

definition thereof. SAFE-BioPharma Association Members sign a separate SAFE-BioPharma Association Member Agreement.

4. Associate Members

- Entities that would otherwise be eligible for membership under another category, that will only use SAFE-BioPharma basic assurance certificates to authenticate to Government managed systems, e.g., EUDRA Vigilance, as a result of acceptance by a Government Agency of such certificate as the directed certificate of use. Certificates issued under this category must meet EU requirements
- Specified and limited personnel employed by business partners who are contractually bound to a Full Members who would use their SAFE-BioPharma credentials for limited business transactions. Examples of such transactions would be related to signing contracts for services such as those between purchasing agents of a member and the specified signatory for the supplying business partner. Employees of organizations which meet the definition of a Full Member are specifically excluded from this category. The employing organization in this case must become SAFE-BioPharma Members. The Full Member would be required, as part of its sponsorship of external parties, to assume complete liability for any transactions signed by the non-member party. The non-member party would be required to sign an associate member agreement. The sponsoring member will ensure that, prior to sponsoring any outside agent for a credential; there is an agreement in force with the employer of the sponsored party that specifies the terms of sponsorship and the limited nature of uses of the SAFE credential. .
- Other Entities designated and sponsored by SAFE-BioPharma.

The following table graphically portrays the different categories and the specific attributes of each.

	WG Participation	System Use	Member Fee Exempt	Credential Fee Paid By	System Governance
Full Members	Yes	Yes	No	Member	Yes
Government Members	Yes	Yes	No	Member	No
Association Member	Yes	No	No	Member	No
Associate Members	Yes	Yes	Yes	Member	No
Other	No	Authentication only	No	Member	No
SAFE-BioPharma Sponsored	No	Yes	Yes	Subscriber	No

2.1.3 SAFE-BioPharma Issuers

SAFE-BioPharma Issuers are Certification Authorities that are contractually bound to the SAFE-BioPharma Standard, including the Operating Policies, for the purpose of providing and managing SAFE-BioPharma Credentials and performing services as a Certification Authority (with all attendant rights and responsibilities under the SAFE-BioPharma Standard) to SAFE-BioPharma Members. The Issuer and Member must enter into a Member Issuer Agreement to provide such services. SAFE-BioPharma Issuers may be Affiliates of SAFE-BioPharma Members or external providers of SAFE-BioPharma Credentials.

SAFE-BioPharma Issuers must be cross certified with the SAFE-BioPharma Bridge Certification Authority (SBCA).

2.1.4 SAFE-BioPharma Stakeholder Agents and Third Parties

SAFE-BioPharma Stakeholders may appoint agents to act on their behalf in respect of their various rights and responsibilities under these Operating Policies, provided that each such agent agrees to comply with all terms and conditions of these Operating Policies that are applicable to its appointed role.

2.1.5 Subscribers

SAFE-BioPharma Subscribers who use SAFE-BioPharma Credentials have a relationship with a SAFE-BioPharma Member as an employee, a business partner, contractor

SAFE-BioPharma Subscribers must sign a Subscriber Agreement with SAFE-BioPharma to use SAFE-BioPharma credentials in compliance with applicable terms and conditions of these Operating Policies and related documents as set forth in the agreement.

Subscribers may be individuals who are nominated by a SAFE-BioPharma Member to obtain a SAFE-BioPharma compliant certificate. Examples of individuals eligible for nomination as a Subscriber include, but may not be limited to, the following

- Individuals who function in a business partner role with a SAFE-BioPharma Member. Depending on the source of the credential the O and OU OIDs may vary, but at least one shall reference the sponsoring Member;
- Employees of Member entities. Either the O and OU in this case shall reference the Member entity;
- Third party contractors working with Members. Either the O and OU in this case shall reference the Member entity;

- Other individuals who, in the judgment of the Member entity, require a SAFE-BioPharma certificate to fulfill a need in support of the Member. In this case the O and OU OIDs are determined on a case by case basis.

2.1.6 Vendor Partners

Vendor partners are not formal members of the SAFE-BioPharma Association, but rather a special class of participant defined as an entity that provides applications, such as software or other hardware and supporting items that provide the technological support required to operate a PKI infrastructure, or otherwise provide specialized consulting services that support Member. Vendor partners may participate in SAFE-BioPharma working groups as a Guest Member and they will be entitled to two SAFE-BioPharma certificates as a benefit of their membership. Additional certificates may be purchased based on specific needs and requests for use in ongoing support activities such as testing, implementation support, etc. Vendor p[artners are eligible to certify their products under the SAFE-BioPharma Product Certification Program.

3. SAFE-BioPharma Operating Policies

SAFE-BioPharma is chartered to develop and manage its operating governance committees and manage the SAFE-BioPharma infrastructure by developing and enforcing SAFE-BioPharma standards through its SAFE-BioPharma Standard Document Set. SAFE-BioPharma developed and manages the SAFE-BioPharma Bridge Certification Authority (SBCA) to provide interoperability across cross-certified Public Key Infrastructures that form the SAFE-BioPharma System. The SBCA is also cross certified with the US Federal Bridge Certification Authority. This further expands the network of trust afforded SAFE-BioPharma Members. As noted in the following section however, transactions across the FBCA may or may not fall under the purview and protection of the SAFE-BioPharma Standard.. The following Sections describe SAFE-BioPharma System Transactions, General Provisions of the Operating Policies, Responsibilities and Requirements of SAFE-BioPharma Stakeholders, and Liabilities and Indemnifications.

These Operating Policies directly apply between and among all SAFE-BioPharma Stakeholders. SAFE-BioPharma Issuers and SAFE-BioPharma Members may deviate from these Operating Policies in their bilateral agreements – SAFE-BioPharma Issuer to SAFE-BioPharma Member and SAFE-BioPharma Member to SAFE-BioPharma Member agreements – except that such deviation may not lead to any additional liability for any other SAFE-BioPharma Stakeholder, and such deviation may not violate a provision of the Operating Policies that requires uniform application in the interest of ensuring the soundness of the SAFE-BioPharma System.

3.1 SAFE-BioPharma System Transactions

With respect to the legal status of a SAFE-BioPharma Digital Signature, SAFE-BioPharma Issuers, SAFE-BioPharma Members, Subscribers, and agents as designated in accordance with Section 2.1.4 agree that when a SAFE-BioPharma Digital Signature is applied to a document, and is processed as a fully compliant SAFE-BioPharma system transaction, the following statements capture the intent of all contracted parties to this agreement. . In terms of identity authentication transactions using SAFE-BioPharma digital certificates, the SAFE-BioPharma Stakeholders agree that the following sections also capture the intent of all parties.

3.1.1 In Scope SAFE-BioPharma System Transactions

A SAFE-BioPharma System Digital Signature Transaction comprises the execution of the following components and steps:

1. Creation of a Digital Signature using a digital certificate issued under the provisions of the SAFE-BioPharma Standard.
2. Creation of a Digital Signature meeting the requirements prescribed by the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines and the SAFE-BioPharma Enabled Applications Technical Specification..
3. Verification by a relying party affiliated with a SAFE-BioPharma Member, of the authenticity of the Digital Signature and validation of the status of the Digital Certificate and its related Certificate Chain from the SAFE-BioPharma Signer's Certificate up to the SAFE-BioPharma Signer's trust

anchor using the steps defined in the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines.

4.

As defined in the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guideline, it is SAFE-BioPharma best practice that recipients verify the validity of the digital signature upon receipt of the document. A SAFE-BioPharma System Transaction shall be recognized under the SAFE-BioPharma Operating Policies upon the completion of the first Verification response by a Relying Party (which may also be the entity who applied the signature). The following tables provide more insight into the meaning of the preceding:

Use Cases – Signature Verified by Signer

Signature Verified	Relying Party	Local Checks	Path Checks	Other Checks	SAFE-BioPharma Transaction
Yes	Signer	Okay	Okay	Okay	Yes
Yes	Signer	Okay	Okay	Not Okay	Yes
Yes	Signer	Okay	Okay	Incomplete	Yes
Yes	Signer	Not Okay	Okay	Okay	No
Yes	Signer	Not Okay	Okay	Not Okay	No
Yes	Signer	Not Okay	Not Okay	Okay	No
Yes	Signer	Not Okay	Not Okay	Not Okay	No
Yes	Signer	Okay	Not Okay	Okay	No
Yes	Signer	Okay	Not Okay	Not Okay	No
Yes	Signer (not SAFE-BioPharma Member)	NA	NA	NA	No

Use Cases – Signature Verified by Relying Party

Signature Verified	Relying Party	Local Checks	Path Checks	Other Checks	SAFE-BioPharma Transaction
--------------------	---------------	--------------	-------------	--------------	----------------------------

					n
Yes	Recipient	Okay	Okay	Okay	Yes
Yes	Recipient	Okay	Okay	Not Okay	Yes
Yes	Recipient	Okay	Okay	Incomplete	Yes
Yes	Recipient	Not Okay	Okay	Okay	No
Yes	Recipient	Not Okay	Okay	Not Okay	No
Yes (signer not a SAFE-BioPharma Member)	Recipient	NA	NA	NA	No
Yes	Recipient (not SAFE-BioPharma Member)	NA	NA	NA	No

Use Cases – Signature Verified by Relying Party (Continued)

Signature Verified	Relying Party	Local Checks	Path Checks	Other Checks	SAFE-BioPharma Transaction
Yes	Recipient	Not Okay	Not Okay	Okay	No
Yes	Recipient	Not Okay	Not Okay	Not Okay	No
Yes	Recipient	Okay	Not Okay	Okay	No
Yes	Recipient	Okay	Not Okay	Not Okay	No

3.1.1.1 Digital Signatures

Digital Signatures are appended to a data object in such a way that any recipient of the data can use the Digital Signature to verify the data's integrity, and the identity of the individual who applied the Digital Signature to the data. Typically, creating a Digital Signature means that the data object is first input into a hash function and the hash result is cryptographically transformed using a Private Key of the signer.

3.1.1.2 Digital Credential Supported Authentication

Digital credential supported authentication is the process whereby a Subscriber uses their digital identity certificate as the authentication mechanism to the infrastructure or applications of a SAFE-BioPharma Member or other relying party that chooses to accept the SAFE-BioPharma credential.

3.1.1.3 Legal Effect

SAFE-BioPharma Association and each SAFE-BioPharma Issuer and SAFE-BioPharma Member agree that; (a) any SAFE-BioPharma System Transaction shall have the same legal effect, validity, and enforceability as if the content of such signed electronic Record had been a manually signed writing; and (b) it will not challenge the legal effect, validity or enforceability of a SAFE-BioPharma System Transaction, an electronic Record or a Digital Signature, on the grounds that the Digital Signature is in electronic form rather than a handwritten signature.

3.1.2 Out of Scope: Non-Safe-Biopharma Signature System Transactions

It is important to note that as SAFE-BioPharma cross certifies the SBCA with other PKI infrastructures, e.g., the Federal Bridge Certification Authority (FBCA), and in this way expands the network of trust from the original closed contract SAFE-BioPharma System, transactions using any certificate other than a SAFE-BioPharma certificate ARE NOT afforded the protection of the SAFE-BioPharma Standard. While such transactions and certificates may be trusted by SAFE-BioPharma Members, they are not covered by the SAFE-BioPharma Transactions Dispute Resolution Process Guideline, nor are they covered under the liability provisions of this document. Cases may also arise in which the signing party does not wish

the resulting signature to be considered a SAFE-BioPharma signature, e.g., the relying party is not a SAFE-BioPharma Member. Such signatures ARE NOT covered by the SAFE-BioPharma Transactions Dispute Resolution Process Guideline, nor are they covered under the liability provisions of this document.

3.2 SAFE-BioPharma Stakeholder Requirements & Responsibilities

The Sections that follow describe the requirements and responsibilities that apply to all SAFE-BioPharma Stakeholders.

3.2.1 Adherence to SAFE-BioPharma Requirements

Each SAFE-BioPharma Stakeholder agrees to comply with the applicable documents as established under the SAFE-BioPharma Standard Document Set.

3.2.2 Intellectual Property Ownership and Licenses

3.2.2.1 Definitions

<u>Licensed Materials</u>	the Specifications and any associated Policies, as may be amended by SAFE-BioPharma pursuant to the SAFE-BioPharma Change Management Process document, and the media or documentation in which such Licensed Materials are recorded or otherwise published, including any updates to or new releases of the same which are made generally available by SAFE-BioPharma.
<u>Policies</u>	any policies, guidelines, standards, agreements or other materials issued by SAFE-BioPharma, including without limitation those policies, guidelines, standards, agreements and other materials contained in the current version of the SAFE-BioPharma Standard Document Set
<u>Products</u>	software, hardware or related functional mechanisms or processes (including without limitation all updates, upgrades and new versions thereof) which are developed by or for a SAFE-BioPharma Issuer or SAFE-BioPharma Member using the Specifications.
<u>Specifications</u>	SAFE-BioPharma's technical and functional requirements for the technology components of the

	SAFE-BioPharma system, including, without limitation, any requirements which may be attached or contained in any Policies, and all know-how, methodologies and processes contained and expressed in and embodied by such Specifications.
<u>Trademarks</u>	all trademarks, trade names, service marks, logos, domain names, IP addresses, designations and insignias owned by SAFE-BioPharma.

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3.2.2.2 Ownership of SAFE-BioPharma Intellectual Property

All SAFE-BioPharma Policies, Specifications, Licensed Materials and Trademarks shall remain the sole and exclusive property of SAFE-BioPharma. SAFE-BioPharma shall retain all rights, title and interest in and to the Policies, Specifications, Licensed Materials and Trademarks including, without limitation, all intellectual property and other proprietary rights throughout the world.

In consideration of the licenses granted by SAFE-BioPharma (as described below), all SAFE-BioPharma Issuers and SAFE-BioPharma Members agree to assign to SAFE-BioPharma all rights, title and interest they may have or acquire in any Licensed Materials and any changes, improvements, modifications, enhancements or derivative works of the Licensed Materials that are discovered, developed, created or conceived by any SAFE-BioPharma Issuer or SAFE-BioPharma Member or any of their employees, directors, subcontractors and agents. However, this assignment shall not include rights to any Products implementing the Specifications, which shall be owned by SAFE-BioPharma Issuers and SAFE-BioPharma Members as provided below. To the extent that a SAFE-BioPharma Issuer or SAFE-BioPharma Member cannot assign or waive any rights they may have or acquire in any Licensed Materials (including any so-called moral rights), such SAFE-BioPharma Issuer or SAFE-BioPharma Member unconditionally and irrevocably grants to SAFE-BioPharma an exclusive, irrevocable, worldwide, perpetual, fully paid and royalty-free license (with rights to sublicense), to reproduce, distribute, publicly perform and display, broadcast, transmit, adapt and/or create derivative works, and otherwise use, assign and transfer the Licensed Materials for any purpose without restriction.

3.2.2.3 Licenses Granted by SAFE-BioPharma

During the period of time that an entity is a SAFE-BioPharma Issuer or SAFE-BioPharma Member, SAFE-BioPharma agrees to grant such SAFE-BioPharma Issuer and SAFE-BioPharma Member (as the case may be) under the terms and conditions of a separate license agreement a non-transferable, non-exclusive, royalty-free license to:

- Use the Licensed Materials solely for purposes of participating in the operation and use of the SAFE-BioPharma System and for creating Products to be used in connection with the operation and use of the SAFE-BioPharma System; and

- Use the SAFE-BioPharma Trademarks in accordance with SAFE-BioPharma's then-current Trademark usage guidelines solely for purposes of indicating the extent to which the SAFE-BioPharma Issuer or SAFE-BioPharma Member (as applicable) participates in the SAFE-BioPharma System.

3.2.2.4 Ownership of Products

Nothing shall be deemed to transfer, convey, assign, license or sell to SAFE-BioPharma, nor shall SAFE-BioPharma have or obtain, any right, title or interest in or to the Products (including, without limitation, any intellectual property and other proprietary rights throughout the world), except for SAFE-BioPharma's right, title and interest in and to the Licensed Materials (and SAFE-BioPharma's intellectual property and other proprietary rights therein).

3.2.2.5 License to SAFE-BioPharma

Each SAFE-BioPharma Issuer and SAFE-BioPharma Member shall grant to SAFE-BioPharma a limited, non-exclusive, worldwide, royalty-free and non-transferable right and license to use the object code of the Products to permit SAFE-BioPharma to certify Products as compatible with the Specifications. Such right and license shall also cover SAFE-BioPharma's right to use the object code for internal research and development. SAFE-BioPharma shall treat all Products and any related documentation as Confidential Information of each particular SAFE-BioPharma Issuer or SAFE-BioPharma Member.

3.2.2.6 Covenant Not to Sue

Each SAFE-BioPharma Issuer and SAFE-BioPharma Member shall covenant not to bring any claim or lawsuit against SAFE-BioPharma or any other SAFE-BioPharma Issuer or SAFE-BioPharma Member in connection with SAFE-BioPharma's or any other SAFE-BioPharma Issuer's or SAFE-BioPharma Member's use or implementation of the Licensed Materials (except for any claim or lawsuit brought to enforce an indemnified party's rights under Sections 3.7.7 and 3.7.8 below) including, without limitation, the creation of any Products in accordance with the Specifications. Such covenant not to sue shall be binding upon any person or entity to which any SAFE-BioPharma Issuer or SAFE-BioPharma Member assigns or otherwise transfers any Products.

3.2.2.7 Use of Specifications Following Termination

Following the point in time that an entity is no longer a SAFE-BioPharma Issuer or SAFE-BioPharma Member, each former SAFE-BioPharma Issuer and former SAFE-BioPharma Member (as the case may be) will retain under the terms and conditions of the license granted by SAFE-BioPharma in accordance with Section 3.2.2.3 above a perpetual, non-transferable, non-exclusive, royalty-free license to internally use the Specifications (as the Specifications exist as of the effective date that the entity is no longer a SAFE-BioPharma Issuer or SAFE-BioPharma Member without any right to any updates to or new releases of the same) solely for purposes of maintaining any Products previously created by or on behalf of such entity.

3.2.3 Confidentiality

3.2.3.1 Definitions.

SAFE-BioPharma Stakeholders acknowledge that they possess and will continue to possess information that has been developed or received by them, that this information has commercial value in their or their customers' business and is not generally available to the public. Except as otherwise specified in this agreement, Confidential Information shall mean any information disclosed by SAFE-BioPharma, any SAFE-BioPharma Issuer, any SAFE-BioPharma Member or any SAFE-BioPharma Stakeholder (hereinafter the "Disclosing Party") to any SAFE-BioPharma Member, SAFE-BioPharma Issuer or SAFE-BioPharma (hereinafter "Receiving Party"), in relation to the establishment of the SAFE-BioPharma System if that information is not generally known and relates to the business of the Disclosing Party, or relates to any material, information or service supplied by or on behalf of, the Disclosing Party, or the SAFE-BioPharma System and/or the services offered by SAFE-BioPharma, if that information is

- Disclosed in tangible form, marked as confidential, restricted or proprietary by the Disclosing Party either before or at the time of disclosure,
- Disclosed orally or visually, designated as confidential, restricted or proprietary either before or at the time of disclosure or otherwise identified in reasonable detail as confidential, restricted or proprietary and confirmed as such in written form delivered to the Receiving Party within 21 days of the date of oral or visual disclosure, or
- Treated as confidential, proprietary or restricted by the disclosing party and would reasonably be understood as such, even if not so marked.

In addition, and regardless of whether such information is specifically marked or identified as "confidential", "proprietary" or "restricted" pursuant to the above paragraph, Confidential Information of SAFE-BioPharma shall include the following:

- Any information concerning the services provided by SAFE-BioPharma or any of its subsidiaries, or the SAFE-BioPharma system and its technologies,
- Any information belonging to SAFE-BioPharma BioPharma or any subsidiaries, in particular, this shall include all contractual agreements, policies, guidelines and specification, any products, processes, services, working models, drawings, samples, prototypes, research, developments, inventions, marketing and business plans, financial statements and information, business projections and proposals, presentations, system architecture, testing plans and results, software object code and source code, specification, documents, or interfaces,
- Records or information that refer to any SAFE-BioPharma Subscriber, SAFE-BioPharma Member or SAFE-BioPharma Issuer, unless the information is being disclosed for a system-imminent purpose which requires public disclosure of information (including in the text of a Certificate),
- Audit results provided either to SAFE-BioPharma and audit results pertaining to SAFE-BioPharma, as long as they are provided or made available according to these Operating Policies.

"Disclosure in tangible form" pursuant to the paragraph above shall mean disclosure of information by electronic transfer either by electronic mail or by delivery on optical, magnetic or other media, either over the Internet or in any other form.

Exceptions. Confidential Information does not include any of the following; if the Receiving Party establishes in writing, or by means of a tangible record that,

- The information at the time of disclosure was generally available to the public other than through a breach of the Receiving Party's or a third party's confidentiality obligations.
- After disclosure to it, the information is published by the Disclosing Party or otherwise becomes generally available to the public other than through a breach of the Receiving Party's or a third party's confidentiality obligations.
- The information is lawfully in the possession of the Receiving Party's at the time of disclosure.
- The information is received from a third party having a lawful right to disclose such information.
- The information is independently developed by the Receiving Party without reference to, access to, or use of Confidential Information of the Disclosing Party.

However, subparagraphs (i) and (ii) of the preceding paragraph shall not apply to the extent that the disclosure or sharing of such information is subject to any limitation, restriction, and consent or notification requirement under any applicable privacy or data protection law. For purposes hereof, the parties agree that Confidential Information that is not generally available to the public shall not be deemed public or subject to these exclusions merely because it is combined with information that is generally available to the public.

3.2.3.2 Confidential Information – Ownership and Obligations

Property and Obligations. The parties agree that all Confidential Information disclosed under the terms of this agreement shall remain the property of the Disclosing Party. Receiving Party shall not disclose Confidential Information for any purpose other than the development, use or operation of the SAFE-BioPharma System and the SAFE-BioPharma services, unless the Disclosing Party has given prior written consent. Receiving Party shall maintain the confidentiality of all Confidential Information received under the terms of this agreement, and use at the least the same degree of care to safeguard and prevent disclosure of Confidential Information to third parties in order to avoid unauthorized disclosure, publication, dissemination, destruction, loss or alteration of its own information, or information of its customers and affiliates, but under no circumstance shall Receiving Party employ less than reasonable care.

Exceptions. Receiving Party may disclose Confidential Information under the following circumstances, namely when the disclosure is:

- Necessary to carry out any aspect of the SAFE-BioPharma service, provided the disclosure is limited to then-current SAFE-BioPharma-Stakeholders, or
- Necessary for the investigation and/or resolution of an alleged error, or
- authorized by a person or entity with an interest in the information, or

- Required by applicable law or to satisfy a legal requirement of a competent government body, such as a subpoena or an order of a court or government or regulatory authority, provided that promptly upon receiving any such request the Receiving Party, to the extent that it may legally do so, advises the Disclosing Party of the Confidential Information to be disclosed prior to making such disclosure, and allowing the Disclosing Party to take action to assure the confidential handling of the information, or any other action it deems appropriate.

Limited Disclosure. Disclosure of Confidential Information pursuant to this agreement shall be limited to the Receiving Party's employees, professional advisors, consultants and representatives who, in order to operate or use the SAFE-BioPharma System and its services, require access to such information. Employees, professional advisors, consultants and representatives to whom Confidential Information is disclosed must be made aware of and instructed to comply with these Operating Policies, including these confidentiality provisions. In no event shall Confidential Information be used by any SAFE-BioPharma Issuer or SAFE-BioPharma Member for purposes other than using or operating the SAFE-BioPharma System, including and without limitation, to prosecute or procure a patent or any other intellectual property right. Except as otherwise allowed pursuant to these confidentiality provisions, no Receiving Party shall use any information obtained from a SAFE-BioPharma Member or SAFE-BioPharma Subscriber that is identifiable to such SAFE-BioPharma Member or Subscriber for any other purpose than to provide the SAFE-BioPharma Services to such Member or Subscriber.

Notice and Cooperation Requirement, Protective Order. In the event of an actual or suspected breach of confidentiality regarding any Confidential Information, the Receiving Party shall promptly notify the Disclosing Party and shall reasonably cooperate in any effort to remedy the breach of confidentiality, or to recover the disclosed information. In the event that the Receiving Party may disclose Confidential Information to satisfy a legal requirement as defined in exception (iv) of the above paragraph, Receiving Party shall use reasonable efforts to cooperate with the Disclosing Party in its efforts to seek a protective order or other appropriate remedy, or in the event that such protective order or remedy is not obtained, to ensure confidential treatment of the information.

No Implied Rights. Nothing contained in this section shall be construed as obligating a party to disclose its Confidential Information to the other party, or as granting to or conferring on a party, expressly or impliedly, any rights or license to any Confidential Information of the other party.

Remedies, Waiver of Defense. In the event of a breach of confidentiality by the Receiving Party pursuant to this agreement, the Disclosing Party shall have the right to (i) receive compensation for actual damages from the Receiving Party for any losses resulting from such breach, this shall include reasonable attorney's fees and legal costs, and (ii) apply for the entry of an immediate order to restrain or enjoin the breach of this agreement, or otherwise specifically enforce the terms of this agreement, either pursuant to the dispute resolution procedures as laid out in the SAFE-BioPharma Accreditation Process document, or to a court of competent jurisdiction. The Receiving Party hereby waives the right to claim as a defense in such legal action that the Information has an adequate remedy at law or in damages and shall not put forth such defense in any legal proceedings.

Termination, Obligation to Destroy and Notice. The Receiving Party shall promptly, but in no event later than within 30 days of the earliest of the following occurrences; (i) request of the Disclosing Party, (ii) termination of the participation of a SAFE-BioPharma Member or SAFE-BioPharma Issuer in the SAFE-BioPharma System, (iii) the completion of the business purpose for which the Confidential Information was required, either return the information to the Disclosing Party, or with the Disclosing Party's consent, destroy the information (and all copies held by the Receiving Party) whether the information was originally provided by the Disclosing Party

or created by the Receiving Party. Receiving Party shall delete or erase all Confidential Information and copies from computer systems, in possession, custody or control of the Receiving Party or any third party to which the Receiving Party disclosed the information, provided that this is possible with commercially reasonable measures. Receiving Party shall deliver to the Disclosing Party within 30 days of any of the above occurrences written certification of its compliance with this section.

Government Organizations. The obligations of a government organization with respect to Confidential Information of a Disclosing Party shall be subject to the terms of these Operating Policies to the fullest extent permitted by law. Each SAFE-BioPharma Member that is a government organization shall protect such Confidential Information from public disclosure under any open records or similar law. To the extent that a SAFE-BioPharma Member that is a government organization is required to retain any Confidential Information beyond the periods specified in these Operating Policies, such government organization shall retain the Confidential Information only for the purposes that require the government organization to retain the Confidential Information, and the obligations of these Operating Policies shall apply to all such retained Confidential Information.

3.2.4 Eligibility

Except where prohibited by applicable law, each prospective SAFE-BioPharma Issuer and prospective SAFE-BioPharma Member applying for participation in the SAFE-BioPharma System shall provide to SAFE-BioPharma any information required by SAFE-BioPharma to certify initial eligibility. Once accredited, each SAFE-BioPharma Issuer or SAFE-BioPharma Member shall comply with all continuing Eligibility requirements as set forth in the SAFE-BioPharma Accreditation Process document, except to the extent prohibited from doing so under any applicable law.

3.2.5 Records

Each SAFE-BioPharma Issuer and SAFE-BioPharma Member shall maintain records in accordance with the requirements specified in the SAFE-BioPharma Digital Signature & Verification Functional Process Guidelines.

3.2.6 Audits

Each SAFE-BioPharma Issuer and SAFE-BioPharma Member must comply with the audit requirements set forth in the SAFE-BioPharma Cross Certification or Member Accreditation Process documents, as applicable.

3.3 SAFE-BioPharma Requirements & Responsibilities

SAFE-BioPharma is chartered to develop and manage its operating governance committees and manage the SAFE-BioPharma System by developing and enforcing the SAFE-BioPharma Standard as embodied in the documents referenced in these Operating Policies. The following Sections define the responsibilities of SAFE-BioPharma in greater detail including management and operating responsibilities, audit compliance requirements, and SAFE-BioPharma systems performance requirements.

3.3.1 Management & Operating Responsibilities

The Sections that follow describe the management and operating responsibilities of SAFE-BioPharma Association.

3.3.1.1 Policies, Rules & Guidelines

SAFE-BioPharma shall develop and make available to the SAFE-BioPharma Issuers and SAFE-BioPharma Members the Operating Policies and other SAFE-BioPharma Guidelines and Specification documents required to conduct SAFE-BioPharma System Transactions.

3.3.1.2 SAFE-BioPharma Stakeholder Management Responsibilities

SAFE-BioPharma shall be responsible for the registration, maintenance, and publishing of a list of all SAFE-BioPharma Cross Certified Issuers and SAFE-BioPharma Accredited Members. In the fulfillment of this activity and to support the interoperability of SAFE-BioPharma Issuers, SAFE-BioPharma will develop and manage a SAFE-BioPharma Bridge Certification Authority (SBCA). In this capacity, SAFE-BioPharma shall issue and maintain such Certificates that may become necessary for the operation of this capability. SAFE-BioPharma shall also cross certify with the Federal Bridge Certification Authority (FBCA) and maintain such cross certification to further extend the ability of SAFE-BioPharma Members to further extend trust to organizations within the Federal Government and other communities cross certified with the FBCA.

3.3.1.3 Audit Responsibilities

SAFE-BioPharma shall execute or direct the execution of audits SAFE-BioPharma deems necessary to ensure the compliance of SAFE-BioPharma Issuers and SAFE-BioPharma Members in accordance with the requirements set forth in the SAFE-BioPharma Member Accreditation and Cross Certification Process documents.

3.3.1.4 Accreditation and Cross Certification Requirements

SAFE-BioPharma shall certify that SAFE-BioPharma Issuers and SAFE-BioPharma Members are compliant with all applicable SAFE-BioPharma Standards.

3.3.1.5 Licensing of SAFE-BioPharma Specification

SAFE-BioPharma shall license and/or certify the use of, depending on the specific case for each SAFE-BioPharma Issuer and SAFE-BioPharma Member, the appropriate SAFE-BioPharma documents to each SAFE-BioPharma Accredited Issuer and SAFE-BioPharma Accredited Member for use by such SAFE-BioPharma Issuer in connection with the SAFE-BioPharma Service.

3.3.2 Audit Compliance Requirements

As required by applicable law or regulation affecting a SAFE-BioPharma Issuer or a SAFE-BioPharma Member, and at the request of such SAFE-BioPharma Issuer or SAFE-BioPharma Member, SAFE-BioPharma agrees to provide government or regulatory agencies access to the systems used by SAFE-BioPharma, and to permit SAFE-BioPharma employees and agents to be interviewed by such government or regulatory agencies in connection with an examination and audit. The requesting SAFE-

BioPharma Issuer or SAFE-BioPharma Member shall reimburse SAFE-BioPharma for the costs incurred by it due to any such examination or audit.

The auditor who performs the audit shall receive approval from and report directly to the SAFE-BioPharma Board of Directors on such matters, and shall (i) be a licensed certified public accountant (CPA); or (ii) hold an appropriate designation (including, without limitation, Certified Information Systems Auditor (CISA), Certified Information Systems Security Practitioner (CISSP), or other designation approved by the SAFE-BioPharma Policy Approval Authority).

Nothing in these Operating Policies limits any independent authority of a government organization that is a SAFE-BioPharma Member to audit SAFE-BioPharma or any other entity if required to do so under separate legal authority.

3.3.3 SAFE-BioPharma Participation as a Member

Upon explicit authorization of the Board of Directors under Section 2.1.2.1 of this document, SAFE-BioPharma, the corporate entity, may participate as a Member in the SAFE-BioPharma System. SAFE-BioPharma will not incur membership fees.

When acting in such a capacity, SAFE-BioPharma shall abide by all relevant SAFE-BioPharma Member provisions of these Operating Policies and any other related document as contained in the SAFE-BioPharma Standard Document Set.

3.4 SAFE-BioPharma Issuer Requirements & Responsibilities

The Sections that follow describe the responsibilities and requirements for SAFE-BioPharma Issuers, which include management responsibilities, operational responsibilities, and technical and operational Standards. In addition to the responsibilities that follow, SAFE-BioPharma Issuers are required to fulfill the roles for SAFE-BioPharma Issuers set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines, the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines, the SAFE-BioPharma Registration and Certificate Management Technical Specification, and the SAFE-BioPharma Functional Specifications.

3.4.1 SAFE-BioPharma Issuer Management Responsibilities

The Sections that follow describe the management responsibilities that must be fulfilled by a SAFE-BioPharma Issuer.

3.4.1.1 Suspension of SAFE-BioPharma Members by SAFE-BioPharma Issuers

SAFE-BioPharma Issuers have an obligation to respond to a SAFE-BioPharma request for SAFE-BioPharma Member suspensions or revocation based on a determination by the SAFE-BioPharma Policy Approval Authority that such action is required.

3.4.1.2 Supplements to Operating Policies

SAFE-BioPharma Issuers shall supplement these Operating Policies, as necessary, with internal policies and guidelines to ensure they remain compliant with these Operating Policies, the SAFE-BioPharma Standard, and all such SAFE-BioPharma Guidelines, and Specifications, including adopting and maintaining a Certificate Policy (CP) and Certificate Practice Statement.

3.4.1.3 Contractual Agreements with SAFE-BioPharma Members

SAFE-BioPharma Issuers shall enter into contractual agreements with SAFE-BioPharma Members to provide Credentials to SAFE-BioPharma Subscribers designated by the SAFE-BioPharma Member.

3.4.1.4 Establish Registration Agents,

SAFE-BioPharma Issuers shall establish Registration Agents to work with SAFE-BioPharma Member Local Registration Agents (if applicable), Trusted Agents or SAFE-BioPharma Requestors and Approvers to manage Credential Life Cycles.

3.4.2 SAFE-BioPharma Issuer Operational Responsibilities

The Sections that follow describe the operational responsibilities that must be fulfilled by a SAFE-BioPharma Issuer.

3.4.2.1 SAFE-BioPharma Transaction Processing

SAFE-BioPharma Issuers shall perform transaction processing functions in accordance with the requirements set forth in the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guideline.

3.4.2.2 Operation of Certificate Registration and Management Systems

SAFE-BioPharma Issuers are responsible for providing Certification Authority and Registration Authority services and systems for use by SAFE-BioPharma Members and Subscribers. These systems must be operated in a manner in compliance with the policies set forth in the SAFE-BioPharma Functional Specification and the SAFE-BioPharma Registration and Certificate Management Technical Specification.

3.4.2.3 Publication and Repositories Responsibilities

SAFE-BioPharma Issuers are responsible for publishing certificate information into repositories available to other SAFE-BioPharma Issuers and SAFE-BioPharma Members for the purpose of verifying the status of issued certificates. Certificate publishing and Certificate Repositories must be operated in a manner in compliance with the policies set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines, the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines, the SAFE-BioPharma Functional Specification, and the SAFE-BioPharma Registration and Certificate Management Technical Specification.

3.4.2.4 Certificate Issuance

SAFE-BioPharma Issuers are responsible for the distribution of Certificates to their contracted SAFE-BioPharma Members and their designated Subscribers in accordance with the minimum standards set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines.

SAFE-BioPharma Issuers, acting in their capacity with SAFE-BioPharma, shall not issue Certificates to Consumers but only to

- A person acting in a professional capacity on behalf of a Member,
- A computer system acting on behalf of a sole proprietor or an Member.

The SAFE-BioPharma Issuer shall require each of its contracted SAFE-BioPharma Members to agree that each act or omission of each of their designated Subscribers shall for all purposes of these Operating Policies be deemed to be an act or omission of the SAFE-BioPharma Member.

3.4.2.5 Issuance of Certificates to Subscribers not Affiliated With, or Sponsored by, a SAFE-BioPharma Member

In no case shall an Issuer provide a SAFE-BioPharma certificate to a subscriber who is not sponsored by, or affiliated with, a SAFE-BioPharma Member.

3.4.2.6 Operational Requirements

SAFE-BioPharma Issuers must establish and operate SAFE-BioPharma Member enrollment processes and issue Certificates in compliance with the policies set forth by SAFE-BioPharma Electronic Identity Management Functional Process Guidelines, the SAFE-BioPharma Functional Specification and the SAFE-BioPharma Registration and Certificate Management Technical Specification.

SAFE-BioPharma Issuers shall establish SAFE-BioPharma Member acceptance policies that establish that the use of a Private Key shall be deemed to be an acceptance of the related Public Key and associated Certificate and the terms and conditions of the SAFE-BioPharma Issuer's Certificate Policy.

SAFE-BioPharma Issuer shall establish and operate key pair and Certificate usage policies for SAFE-BioPharma Members in compliance with the policies set forth in the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines.

SAFE-BioPharma Issuers shall establish and operate Certificate revocation and suspension services in conjunction with its Certification Authority and Registration Authority services and in a manner in compliance with the policies set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines.

3.4.2.7 Certificate Status Services System Requirements

Except where otherwise prohibited under any applicable law, a SAFE-BioPharma Issuer shall make reasonable efforts to be continuously available (twenty-four hours a day, every day of the year) to respond to requests for the validation of the status of the Digital Certificate and its related Certificate Chain from the SAFE-BioPharma Signer's Certificate up to the SAFE-BioPharma Signer's trust anchor using the steps defined in the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines, the SAFE-BioPharma Registration and Certificate Management Technical Specification, and

the SAFE-BioPharma Functional Specifications. SAFE-BioPharma Issuers shall take reasonable steps to ensure such availability, including appropriate planning for emergencies and contingencies and implementation of contingency operations procedures

Ninety calendar days (90) prior to the end of each year, each SAFE-BioPharma Issuer shall identify and disclose to SAFE-BioPharma and its contracted SAFE-BioPharma Members any days or portions of days during the next year when the SAFE-BioPharma Issuer will be prohibited by law from responding to SAFE-BioPharma System Transactions. SAFE-BioPharma Issuers shall also give SAFE-BioPharma and their respective contracted SAFE-BioPharma Members prompt notice of any changes in the previously disclosed schedule.

A SAFE-BioPharma Issuer shall operate a time clock as part of its computer system that records the time of various SAFE-BioPharma Issuer operating activities as set forth in the SAFE-BioPharma Registration and Certificate Management Technical Specification and in the SAFE-BioPharma Certificate Policy (SAFE-BioPharma CP). The time established on this time clock shall be based on a reliable time source selected by the SAFE-BioPharma Issuer, and shall operate on the Coordinated Universal Time (UTC) standard. SAFE-BioPharma may require the SAFE-BioPharma Issuer to select another reliable time source.

A SAFE-BioPharma Issuer shall include a time stamp on each SAFE-BioPharma System Transaction it processes. The time stamp shall comply with the formats and parameters set forth in SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines, the SAFE-BioPharma Registration and Certificate Management Technical Specification, and the SAFE-BioPharma CP.

3.4.2.8 Certificate, CRL, and OCSP Profiles

SAFE-BioPharma Issuers shall:

1. issue Certificates that comply with the SAFE-BioPharma Certificate Policy (SAFE-BioPharma CP).
2. issue Certificate Revocation Lists (CRL) in a manner that complies with the SAFE-BioPharma CRL Profile and the SAFE-BioPharma CP.
3. operate OCSP systems in a manner that complies with the SAFE-BioPharma OCSP Profile and the SAFE-BioPharma CP.

3.4.3 Technical and Operational Controls

The Sections that follow describe the Technical and Operational Controls that must be implemented by the SAFE-BioPharma Issuers.

3.4.3.1 Facility, Management, and Operational Controls

SAFE-BioPharma Issuers shall ensure that all physical controls, procedural controls, personnel controls, and audit logging procedures associated with its Certification Authority and Registration Authority systems are formally established into a SAFE-BioPharma Issuer CPS and controlled in a manner in compliance with the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines. Once established, the requirements for the Certification Authority and Registration Authority shall be set forth in the Issuer CP and compliance with the SAFE-BioPharma Issuer's SAFE-BioPharma CP shall be established in a SAFE-BioPharma Issuer Certification Practices Statement (CPS).

SAFE-BioPharma Issuers must ensure proper records and audit log archives are created and maintained in compliance with the requirements set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines and SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines in order to support SAFE-BioPharma Dispute Resolution proceedings and any SAFE-BioPharma Member compliance requirements with applicable law.

SAFE-BioPharma Issuers shall establish formal operational procedures and controls in compliance with the requirements set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines for SAFE-BioPharma Issuer key changeover, key compromise, and disaster recovery and for Certification Authority or Registration Agent termination from the SAFE-BioPharma System, and once established, the SAFE-BioPharma CP.

3.4.3.2 Technical Security Controls

SAFE-BioPharma Issuers shall establish technical security controls in compliance with the SAFE-BioPharma Functional Specification, the SAFE-BioPharma Registration and Certificate Management Technical Specification, and the SAFE-BioPharma End-Subscriber Systems Technical Specification to control both its and its SAFE-BioPharma Member's performance of various technical functions, including key pair generation and installation procedures, Private Key protection and cryptographic module engineering controls, Certificate activation data, computer security controls, life cycle technical controls, Network security controls, and time-stamping.

3.4.3.3 Contingency Plans

SAFE-BioPharma Issuers shall maintain contingency plans in force, including adequate back up and disaster recovery procedures, to ensure that the SAFE-BioPharma Issuer can continue to meet its obligations under these SAFE-BioPharma Operating Policies without material interruption in the event of the failure or shut down of the SAFE-BioPharma Issuer's primary computer facilities or other operating facilities.

A SAFE-BioPharma Issuer shall notify SAFE-BioPharma as soon as reasonably possible if it transfers any portion of its SAFE-BioPharma related operational or technical systems to its back-up or recovery facilities if such transfer will affect the ability of the SAFE-BioPharma Issuer to meet its SAFE-BioPharma obligations under these Operating Policies.

3.5 SAFE-BioPharma Member Requirements & Responsibilities

The Sections that follow describe the responsibilities and requirements for SAFE-BioPharma Members, which include management responsibilities and operational responsibilities. In addition to the responsibilities that follow, SAFE-BioPharma Members are required to fulfill the roles for SAFE-BioPharma Members set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines, the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines, and the SAFE-BioPharma Functional Specifications.

3.5.1 SAFE-BioPharma Member Management Responsibilities

The Sections that follow describe the management responsibilities that must be fulfilled by SAFE-BioPharma Members.

3.5.1.1 Supplement Operating Policies and Relevant Documents

SAFE-BioPharma Members shall supplement these Operating Policies, as necessary, with internal policies and guidelines to ensure they remain compliant with these Operating Policies and related applicable documents as set forth in the SAFE-BioPharma Standard Document Set.

3.5.1.2 Contractual Agreements with SAFE-BioPharma Issuers

SAFE-BioPharma Members shall enter into a contractual agreement (or, as applicable in the context of a government organization that is a SAFE-BioPharma Member, an alternative, legally-binding relationship) with:

- SAFE-BioPharma Accredited Issuer to provide Credentials to SAFE-BioPharma Subscribers designated by the SAFE-BioPharma Member

3.5.1.3 Policies and Procedures

Each SAFE-BioPharma Member acknowledges that it is familiar with, and agrees to comply with, the policies and procedures established by SAFE-BioPharma Issuers relating to each SAFE-BioPharma Issuer's issuance, expiration and revocation of Certificates.

Each SAFE-BioPharma Member also shall establish internal policies and guidelines to verify Subscriber identities to a SAFE-BioPharma Issuer under the terms of its SAFE-BioPharma Issuer to SAFE-BioPharma Member agreement. They also shall supplement the SAFE-BioPharma Electronic Identity Management Functional Process Guideline and the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guideline, as required, to meet internal business processes.

3.5.1.4 Establish Roles and Responsibilities

SAFE-BioPharma Members shall:

- Designate SAFE-BioPharma Subscribers as it deems appropriate for the purpose of obtaining SAFE-BioPharma Credentials; and
- In the case of Members that use the SAFE-BioPharma Registration Authority System, establish internal SAFE-BioPharma Requestors and Approvers with the responsibility for processing Subscriber Requests for Credentials and managing Credential Life Cycle according to established SAFE-BioPharma and SAFE-BioPharma Member Policies and Guidelines;

3.5.1.5 Notifications

SAFE-BioPharma Members shall notify SAFE-BioPharma Issuers of any changes to any designated subscriber's status according to contractual agreements and applicable SAFE-BioPharma and SAFE-BioPharma Member guidelines.

3.5.2 SAFE-BioPharma Member Operational Responsibilities

The Sections that follow describe the Operational Responsibilities that must be fulfilled by a SAFE-BioPharma Member.

3.5.2.1 Issuance of Certificates to Subscribers

SAFE-BioPharma Members shall direct the issuance of Certificates to Subscribers according to the following requirements:

- SAFE-BioPharma Members are responsible for the issuance of Certificates to their Subscribers in accordance with minimum standards set forth in the SAFE-BioPharma Electronic Identity Management Functional Process Guidelines.
- SAFE-BioPharma Members shall not direct SAFE-BioPharma Issuers to issue Certificates to Consumers, but only to natural persons acting in a professional capacity on behalf of the Member. .
- A SAFE-BioPharma Member may designate partners, contractors and other authorized Affiliates of that SAFE-BioPharma Member to be issued a SAFE-BioPharma Certificate and participate in the SAFE-BioPharma System and have SAFE-BioPharma Issuers directed to issue to such parties, employees or agents. In such instance where a SAFE-BioPharma Member holds less than 50% of the voting rights of an otherwise qualified Affiliate, it shall not direct Issuers to issue Certificates to such Affiliate's Subscribers unless it has obtained a legally binding and unconditional assurance from such Affiliate that such Affiliate will follow instructions issued by the SAFE-BioPharma Member relating to the participation in the SAFE-BioPharma System.
- SAFE-BioPharma Members may deploy SAFE-BioPharma Credentials as part of an automated process to either create and/or verify Digital Signatures. The software and/or hardware responsible for performing these functions are regarded as Machine User. The Machine Operator and Machine User together are the legal equivalent of a single Subscriber.
- The SAFE-BioPharma Member agrees that each act or omission of each of its designated Subscribers shall for all purposes of these SAFE-BioPharma Operating Policies be deemed to be, to the extent permitted by law, an act or omission of the SAFE-BioPharma Member.

3.5.2.2 Warranty of Accuracy

Each SAFE-BioPharma Member hereby warrants the accuracy of any information submitted to its contracted SAFE-BioPharma Issuer during the Certificate issuance or Certificate validation processes for its designated Certificate Holders.

3.5.2.3 Required Notice

Each SAFE-BioPharma Member shall provide timely and accurate notice to its contracted SAFE-BioPharma Issuer of information relating to (a) circumstances that may affect the validity and/or accuracy of its Private Key/Public Key Pair(s) and/or Certificate(s), or (b) any compromise or suspected compromise of the security of its computer systems or Smart Card(s) on which the SAFE-BioPharma Member's SAFE-BioPharma Subscriber's Private Key is stored.

3.5.2.4 SAFE-BioPharma Certificate Validation

Each SAFE-BioPharma Member, when acting as a Relying Party, agrees that before relying upon a SAFE-BioPharma Subscriber's Digital Signature, it will validate that Digital Signature and its associated Certificate pursuant to the requirements of the SAFE-BioPharma Digital Signature Use & Verification

Functional Process Guidelines, the SAFE-BioPharma Functional Specification, and the SAFE-BioPharma Enabled Applications Technical Specification.

3.5.2.5 Compliance with Instructions

Each SAFE-BioPharma Member shall only perform SAFE-BioPharma System Transactions in accordance with the applicable provisions of these Operating Policies and the terms of its SAFE-BioPharma Issuer to SAFE-BioPharma Member agreement.

3.5.2.6 Consent to Use of Information

Each SAFE-BioPharma Member agrees that other SAFE-BioPharma Stakeholders, including their agents, may use, including transmit, receive, or process, information regarding the SAFE-BioPharma Member and its subscribers among and between themselves and other third parties for the purpose of providing SAFE-BioPharma System Transactions and the resolution of disputes arising from SAFE-BioPharma System Transactions. This consent is limited to the extent that such use of information is permissible under applicable law and necessary for achieving the mentioned purpose. The SAFE-BioPharma Member shall obtain the consent of its Subscribers where applicable law requires such consent.

3.5.2.7 Safekeeping

SAFE-BioPharma Members shall safe keep their Private Key(s) in accordance with the SAFE-BioPharma CP.

3.5.2.8 Prohibited Transactions

SAFE-BioPharma Members shall not use their Certificates, or the SAFE-BioPharma Services in connection with a Digital Record involving any of the following types of transactions: (a) any transaction prohibited by applicable law; or (b) any transaction prohibited under the terms and conditions of a SAFE-BioPharma Issuer agreement.

3.5.2.9 Contingency Plans

SAFE-BioPharma Members shall maintain adequate back up and disaster recovery procedures, to ensure that the SAFE-BioPharma Member can continue to meet its obligations under these SAFE-BioPharma Operating Policies at all times without material interruption in the event of the failure or shut down of the SAFE-BioPharma Member's primary operating facilities.

3.5.3 SAFE-BioPharma Transaction Processing

SAFE-BioPharma Members shall perform transaction processing functions in accordance with the requirements set forth in the SAFE-BioPharma Digital Signature Use & Verification Functional Process Guidelines.

3.6 General Provisions of the Operating Policies

The Section that follows describes the General Provisions of these Operating Policies, which covers all SAFE-BioPharma Participants.

3.6.1 Operating Policy Administration

The Sections that follow describe the administrative provisions and requirements associated with the Operating Policies that are carried out by the SAFE-BioPharma Policy Approval Authority.

3.6.1.1 Order of Precedence and Resolution of Inconsistency

In the event of an inconsistency between any term or provision of these Operating Policies and the provisions of any other document comprising the SAFE-BioPharma Standard Document Set (but excluding any bilateral agreements - SAFE-BioPharma Issuer to SAFE-BioPharma Member and SAFE-BioPharma Member to SAFE-BioPharma Member agreements - which are subject to the provisions of the second paragraph of Section 3 above), the terms and provisions of these Operating Policies shall take precedence over the other inconsistent terms. This English version of the Operating Policy is the official and binding document, and any inconsistency between this version and translated versions shall be resolved according to the terms and reasonable inferences drawn from this English version.

3.6.1.2 Amendment to the SAFE-BioPharma Operating Policies

The SAFE-BioPharma Policy Approval Authority is responsible for issuing the initial Operating Policies and for subsequent amendments.

3.6.1.3 Notice Procedures

The SAFE-BioPharma Policy Approval Authority shall ensure that all SAFE-BioPharma Stakeholders shall be put on notice of any substantive change(s) to these Operating Policies. All notices, requests, consents, approvals, agreements, authorizations, acknowledgments, waivers and other communications required or permitted under these Operating Policies shall be in writing, electronic or otherwise, signed using a SAFE-BioPharma Credential or otherwise, and delivered to the party designated to receive such notices under each applicable SAFE-BioPharma Issuer Agreement, SAFE-BioPharma Member Agreement or other relevant document.

3.6.1.4 Counterparts

These Operating Policies may be executed in any number of counterparts, each of which will be deemed an original, but all of which taken together shall constitute one single agreement among the SAFE-BioPharma Stakeholders.

3.6.1.5 Entire Agreement

These Operating Policies and the policies, guidelines and specifications referenced herein represent the entire agreement and understanding among the SAFE-BioPharma Stakeholders with respect to the subject matter hereof and supersede all prior agreements and understandings relating to such subject matter, and there are no other representations, understandings or agreements among the SAFE-BioPharma Stakeholders relative to such subject matter.

3.6.1.6 Waivers

Except where an express time frame is set forth in these Operating Policies, no delay or omission by any party to exercise any right, remedy or power it has under these Operating Policies shall impair or be construed as a waiver of such right, remedy or power. A waiver by any party of any breach or covenant in these Operating Policies shall not be construed to be a waiver of any other or succeeding breach or covenant.

3.6.2 General Effects on SAFE-BioPharma Stakeholders

The Section that follows describes the general effects the Operating Policies will have on the SAFE-BioPharma Stakeholders.

3.6.2.1 Enforcement of the Operating Policies

These Operating Policies and the rights and obligations of all SAFE-BioPharma Stakeholders hereunder shall be governed and construed in accordance with the laws of the State of New York as such laws are applied to agreements entered into and to be performed entirely within New York, without giving effect to the principles thereof relating to the conflicts of laws. This Section 3.6.2.1 is subject to contrary requirements of law applicable to SAFE-BioPharma Members that are Government Organizations.

3.6.2.2 Assignment

Except in the case of a transfer of all or substantially all of the assets of a SAFE-BioPharma Issuer or SAFE-BioPharma Member, these Operating Policies and the rights, obligations and remedies hereunder shall not be assignable or transferable by any SAFE-BioPharma Issuer or SAFE-BioPharma Member without the prior consent of SAFE-BioPharma (to be given in its sole discretion). SAFE-BioPharma's consent to any assignment of these Operating Policies shall not constitute SAFE-BioPharma's consent to further assignment. These Operating Policies shall be binding on the SAFE-BioPharma Stakeholders and their respective successors and permitted assigns. Any assignment in contravention of this Section shall be void.

3.6.2.3 Relationship of the SAFE-BioPharma Stakeholders

These Operating Policies are not intended, and shall not be construed, to create a corporation, partnership, joint venture, agency relationship or other legally recognized entity by or among SAFE-BioPharma and SAFE-BioPharma Issuers or SAFE-BioPharma Members. SAFE-BioPharma Issuers and SAFE-BioPharma Members shall not have any power to enter into any agreement or obligation on behalf of other participants in the SAFE-BioPharma System without the express written authorization of SAFE-BioPharma or such other SAFE-BioPharma Issuers or SAFE-BioPharma Members, as the case may be.

3.6.2.4 Third Party Beneficiaries

These Operating Policies are for the sole benefit of the SAFE-BioPharma Stakeholders and their permitted assigns and each party intends that these Operating Policies shall not benefit, or create any right or cause of action in or on behalf of, any person or entity other than the SAFE-BioPharma Stakeholders and their permitted assigns.

3.6.3 Third Party Providers

SAFE-BioPharma, SAFE-BioPharma Issuers, and SAFE-BioPharma Members may subcontract any portion of their obligations under these Operating Policies to third parties. SAFE-BioPharma Stakeholders Participants shall not disclose any of the other parties' Confidential Information to any such subcontractor unless and until such subcontractor has agreed in writing to protect the confidentiality of such Confidential Information in a manner no less restrictive than that required under these Operating Policies, and then only to the extent necessary for such subcontractor to perform the obligations subcontracted to it. In addition, SAFE-BioPharma Issuers and SAFE-BioPharma Members shall ensure that any obligations subcontracted to any third party may be audited by SAFE-BioPharma or applicable regulators in accordance with the provisions of these Operating Policies. SAFE-BioPharma and each SAFE-BioPharma Issuer and SAFE-BioPharma Member shall remain responsible for the obligations performed by any of its subcontractor to the same extent as if such obligations were performed by SAFE-BioPharma or each SAFE-BioPharma Issuer and SAFE-BioPharma Member itself.

3.6.4 Dispute Resolution

Except for any disputes arising out of a SAFE-BioPharma Stakeholder's breach of confidentiality obligations hereunder or infringement of another SAFE-BioPharma Stakeholder's intellectual property rights, the SAFE-BioPharma Stakeholders agree to resolve any dispute arising out of or in connection with these Operating Policies in accordance with the SAFE-BioPharma Transaction Dispute Resolution

Process document and the SAFE-BioPharma Accreditation Process document. The only remedy available against SAFE-BioPharma in any such dispute resolution proceeding shall be monetary damages, subject to the limits set forth in these Operating Policies. For purposes of clarity, SAFE-BioPharma Stakeholders acknowledge that they may agree in bilateral agreements executed between each other to use other dispute resolution procedures with respect to issues outside the scope of these Operating Policies and dealt with in such bilateral agreements. This Section 3.6.4 is subject to contrary requirements of law applicable to SAFE-BioPharma Members that are government organizations.

3.6.5 Compliance with Applicable Law

Each SAFE-BioPharma Stakeholder is responsible for conducting its responsibilities under these Operating Policies in compliance with any applicable law, including applicable laws governing digital signatures, Certificate authorities, public key/private key or asymmetric cryptography, encryption export or import restrictions, personal and other data privacy and anti-trust or competition. A SAFE-BioPharma Issuer is responsible for obtaining any required approval or consent from any Subscriber, and providing any required notice to all applicable government authorities and Subscribers prior to offering any SAFE-BioPharma related services to any SAFE-BioPharma Member.

3.7 Liabilities, Warranties and Indemnifications

3.7.1 Recourse

To the extent permitted by law, each SAFE-BioPharma Stakeholder shall have recourse against any other SAFE-BioPharma Stakeholder for any damage resulting from a breach of the terms and conditions of these Operating Policies by such other SAFE-BioPharma Stakeholder. In addition, SAFE-BioPharma Stakeholders may have additional recourse or liability to other SAFE-BioPharma Stakeholders under the terms and conditions of any bilateral agreement(s) executed with such other SAFE-BioPharma Stakeholders and otherwise as provided under applicable law.

3.7.2 Breach of Contract

In the event of an alleged breach of contract, any SAFE-BioPharma Stakeholder may bring a breach of contract claim against any other SAFE-BioPharma Stakeholder. A breach of contract pursuant to this provision includes any alleged breach of any provisions of the Operating Policies, the SAFE-BioPharma Standard or any Policies, Guidelines and Specifications contained therein or attached thereto.

3.7.2.1 Limitation of Liability

These Operating Policies create neither a duty of care other than specifically provided for in this agreement, nor a special relationship of trust and confidence between and/or among SAFE-BioPharma and any SAFE-BioPharma Member or SAFE-BioPharma Issuer. The SAFE-BioPharma Stakeholders hereby expressly limit any liability or claim for tort arising out of these Operating Policies, including for negligent performance of this contract, to liability or claims for gross negligence and willful misconduct

only. Also excluded among SAFE-BioPharma Stakeholders is any liability or claim arising out of a violation of an applicable statute or regulation.

3.7.2.2 Limitation of Damages

In no event shall a SAFE-BioPharma Stakeholder be liable to any other SAFE-BioPharma Stakeholder for indirect, consequential, incidental, collateral, exemplary or punitive damages, including lost profits, regardless of the form of the action or the theory of recovery, even if such Stakeholder has been advised of the possibility of such damages.

3.7.3 Minimum Amount, Liability Cap

SAFE-BioPharma Stakeholders may recover damages from any other SAFE-BioPharma Stakeholder for any claim arising out of or in connection with these Operating Policies only if such damages resulting from any breach (or a series of breaches arising out of the same set of circumstances) exceed, in the aggregate, the sum of five thousand U.S. dollars (US \$5,000). The entire amount may be recovered if such damages exceed five thousand U.S. dollars (U.S. \$5,000). For SAFE-BioPharma Issuers and SAFE-BioPharma Members, such liability for any breach (or a series of breaches arising out of the same set of circumstances) shall be limited to five hundred thousand U.S. dollars (US \$500,000). The aggregate annual liability of each SAFE-BioPharma Member or SAFE-BioPharma Issuer shall be limited to ten million U.S. dollars (US \$10,000,000).

Additionally, the total aggregate liability of SAFE-BioPharma, for claims asserted by any SAFE-BioPharma Stakeholder, under or in connection with this agreement, regardless of the form of the action or theory of recovery, shall be limited to the amount of the monthly transaction/Subscriber fees actually received from a SAFE-BioPharma Issuer or SAFE-BioPharma Member for the specific service provided by SAFE-BioPharma–BioPharma out of which the claim arose, during the month immediately prior to the occurrence.

3.7.4 Exceptions

The limitations and exculpations set forth in Sections 3.7.2.2 and 3.7.3.2 shall not apply to (a) indemnification claims under Sections 3.7.7 and 3.7.8, (b) a SAFE-BioPharma Stakeholder's breach of its confidentiality obligations hereunder or (c) a SAFE-BioPharma Stakeholder's infringement of another SAFE-BioPharma Stakeholder's intellectual property rights.

3.7.5 Statute of Limitations

For the purposes of resolving disputes and settling monetary claims under these Operating Policies, the maximum timeframe within which a SAFE-BioPharma Signatory to these Operating Policies may bring a claim against another SAFE-BioPharma Signatory shall be the shorter of:

- Two (2) years from the point at which the claimant discovers the cause of action; or
- The time period set forth in the statute of limitations of the State of New York.

3.7.6 Force Majeure

No SAFE-BioPharma Stakeholder shall be liable for any default or delay in the performance of its obligations under these Operating Policies if and to the extent such default or delay is caused, either directly or indirectly, by any of the following:

- Any provision of any present or future law, regulation or order of the United States of America, or any state thereof, or any foreign country, or any subdivision thereof, or of any court of competent jurisdiction insofar as such law, regulation or order is applicable to the SAFE-BioPharma Stakeholder,
- By failure of any electrical, communication or other system operated by third parties other than the SAFE-BioPharma Stakeholder and its Third Party Processor,
- Fire, flood, earthquake, or any act of God, war, terrorist attack or other emergency condition beyond the control of the SAFE-BioPharma Stakeholder, except to the extent that the non-performing SAFE-BioPharma Stakeholder is at fault in failing to prevent or causing such default or delay, and provided that such default or delay cannot reasonably be circumvented by the non-performing SAFE-BioPharma Stakeholder through the use of commercially reasonable alternate plans.

In the event of a force majeure event, the non-performing SAFE-BioPharma Stakeholder shall be excused from further performance or observance of the obligations affected for as long as such circumstances prevail and such SAFE-BioPharma Stakeholder continues to use all commercially reasonable efforts to recommence performance or observance. Any SAFE-BioPharma Stakeholder so prevented, hindered or delayed in its performance shall, as quickly as practicable under the circumstances, notify the other SAFE-BioPharma Stakeholders to whom performance is due by telephone and describe in reasonable detail the circumstances of the force majeure event, the steps being taken to address such event, and the expected duration of such force majeure event.

3.7.7 Indemnifications

3.7.7.1 Indemnification by SAFE-BioPharma Issuers

Each SAFE-BioPharma Issuer agrees to indemnify, defend and hold harmless SAFE-BioPharma any other SAFE-BioPharma Issuer and SAFE-BioPharma Member as well as their officers, directors, employees, agents, representatives, successors, and assigns, from and against any and all liability, losses or expense, including reasonable attorney fees, incurred by SAFE-BioPharma a SAFE-BioPharma Issuer or SAFE-BioPharma Member, or their respective officers, directors, employees, agents, representatives, successors, and assigns, due to a third party claim arising out of participation in the SAFE-BioPharma system, limited to the following set of circumstances: the indemnifying SAFE-BioPharma Issuer has provided a SAFE-BioPharma service to a party that is not bound by a SAFE-BioPharma Issuer-SAFE-BioPharma Member agreement containing liability limitations corresponding to its role (as Relying or Subscribing Member) with respect to its use of or reliance upon the SAFE-BioPharma service, and a third party claim based on the provision of this service has been brought against another SAFE-BioPharma Issuer, SAFE-BioPharma Member or SAFE-BioPharma.

In no event shall a SAFE-BioPharma Issuer be obliged to indemnify a third party with respect to its own gross negligence, willful misconduct, or for the award of any punitive or exemplary damages. A SAFE-BioPharma Issuer's obligation to indemnify SAFE-BioPharma shall not exceed the liability of SAFE-BioPharma to that SAFE-BioPharma Issuer under these Operating Policies with respect to the same set of circumstances.

3.7.7.2 Indemnification by SAFE-BioPharma Members

Each SAFE-BioPharma Member agrees to indemnify, defend and hold harmless SAFE-BioPharma BioPharma and any SAFE-BioPharma Issuer as well as their officers, directors, employees, agents, representatives, successors, and assigns, from and against any and all liability, losses or expense, including reasonable attorney fees, incurred by SAFE-BioPharma BioPharma, a SAFE-BioPharma Issuer or their respective officers, directors, employees, agents, representatives, successors, and assigns, due to a third party claim arising out of participation in the SAFE-BioPharma system, limited to the following sets of circumstances:

- The indemnifying SAFE-BioPharma Member engaged in conduct which led to an erroneous issuance of a "Valid Certificate Status Response" with respect to a certificate registered to the indemnifying Member,
- The indemnifying SAFE-BioPharma Member failed to comply with the terms of the SAFE-BioPharma Issuer – SAFE-BioPharma Member Agreement in effect between the indemnifying Member and its SAFE-BioPharma Issuer,
- The indemnifying SAFE-BioPharma Member used its Certificates with electronic messages or communications sent to third parties that are not SAFE-BioPharma participants,

In no event shall a SAFE-BioPharma Member be obliged to indemnify a third party with respect to its own gross negligence, willful misconduct, or for the award of any punitive or exemplary damages. A SAFE-BioPharma Member's obligation to indemnify SAFE-BioPharma shall not exceed the liability of SAFE-BioPharma to that SAFE-BioPharma Member under these Operating Policies with respect to the same set of circumstances.

3.7.8 Intellectual Property Indemnification

3.7.8.1 Indemnity from SAFE-BioPharma.

SAFE-BioPharma shall indemnify and defend each SAFE-BioPharma Issuer and SAFE-BioPharma Member and hold each SAFE-BioPharma Issuer and SAFE-BioPharma Member harmless from and against all damages, fines, penalties, deficiencies, losses, liabilities (including, without limitation, settlements and judgments), costs or expenses (including, without limitation, interest, court costs, reasonable fees and expenses of attorneys) suffered, incurred or sustained by a SAFE-BioPharma Issuer or SAFE-BioPharma Member or to which a SAFE-BioPharma Issuer or SAFE-BioPharma Member becomes subject, resulting from, arising out of or relating to any third party claim that the Licensed Materials or any Trademark infringe upon the rights (including proprietary rights) of any third party (except as may have been caused by a SAFE-BioPharma Issuer or SAFE-BioPharma Member).

3.7.8.2 Indemnity from SAFE-BioPharma Issuers and SAFE-BioPharma Members.

Each SAFE-BioPharma Issuer and SAFE-BioPharma Member shall indemnify and defend SAFE-BioPharma and hold SAFE-BioPharma harmless from and against all damages, fines, penalties, deficiencies, losses, liabilities (including, without limitation, settlements and judgments), costs or expenses (including, without limitation, interest, court costs, reasonable fees and expenses of attorneys) suffered, incurred or sustained by SAFE-BioPharma or to which SAFE-BioPharma becomes subject, resulting from, arising out of or relating to any third party claim that any Product infringes upon the rights (including proprietary rights) of any third party (except as may have been caused by SAFE-BioPharma).

3.7.8.3 Additional SAFE-BioPharma Obligations.

In addition to the requirements of Section 3.7.8.1 above, if the use of any Licensed Material or any Trademark is enjoined or if SAFE-BioPharma believes that any Licensed Material or any Trademark is infringing, SAFE-BioPharma shall, at its expense, use commercially reasonable efforts to procure for the behalf of all then-current SAFE-BioPharma Issuers and SAFE-BioPharma Members a license allowing such SAFE-BioPharma Issuers and SAFE-BioPharma Members to continue using the Licensed Material or Trademark in accordance with these Operating Policies and their applicable license agreement with SAFE-BioPharma. If SAFE-BioPharma is unable to do so, SAFE-BioPharma shall, at its own expense, use commercially reasonable efforts to: (a) replace the Licensed Material or Trademark with non-infringing material or a non-infringing mark which enables SAFE-BioPharma Issuers and SAFE-BioPharma Members to continue using the SAFE-BioPharma System; (b) modify the Licensed Material or Trademark to be non-infringing, so long as the modified material or mark enables SAFE-BioPharma Issuers and SAFE-BioPharma Members to continue using the SAFE-BioPharma System; or (c) if after exercising commercially reasonable efforts SAFE-BioPharma is unable to replace or modify the Licensed Material or Trademark as stated above, terminate the applicable license(s) granted in accordance with Sections 3.2.2.3 and 3.2.2.7 above.

3.7.8.4 Additional SAFE-BioPharma Issuer and SAFE-BioPharma Member Obligations.

In addition to the requirements of Section 3.7.8.2 above, if the use of any Product is enjoined or if the SAFE-BioPharma Issuer or SAFE-BioPharma Member that owns any Product believes that such Product is infringing, such SAFE-BioPharma Issuer or SAFE-BioPharma Member shall, at its expense, use commercially reasonable efforts to procure for the behalf of SAFE-BioPharma a license allowing SAFE-BioPharma to continue using such Product in accordance with these Operating Policies and its applicable license agreement with SAFE-BioPharma. If such SAFE-BioPharma Issuer or SAFE-BioPharma Member is unable to do so, such SAFE-BioPharma Issuer or SAFE-BioPharma Member shall, at its own expense, use commercially reasonable efforts to: (a) replace the Product with a non-infringing product; (b) modify the Product to be non-infringing; or (c) if after exercising commercially reasonable efforts such SAFE-BioPharma Issuer or SAFE-BioPharma Member is unable to replace or modify the Product as stated above, terminate the applicable license(s) granted in accordance with in Section 3.2.2.5 above.

3.7.9 Other Provisions

Except as specifically provided in these Operating Policies, SAFE-BioPharma shall have no liability to any SAFE-BioPharma Issuer, SAFE-BioPharma Member, SAFE-BioPharma Subscriber or other entity or person for any loss, claim, damage or expense arising from SAFE-BioPharma's or their participation in any way in the SAFE-BioPharma System or the offering of any SAFE-BioPharma Service to SAFE-BioPharma Members, SAFE-BioPharma Subscribers or other entities or persons.

3.7.10 Government Organizations

To the extent that a SAFE-BioPharma Member that is a government organization is not permitted by law to bind itself to the defense, indemnification and hold harmless obligations set forth in these Operating Policies or to make payments as required under said obligations, the SAFE-BioPharma Member shall endeavor to the extent feasible to provide remedies as closely approximating the purpose of such obligations, including, without limitation, by requesting appropriations to permit the making of payments to indemnified entities.

3.7.11 Disclaimer Of Warranties

Except as expressly set forth in these operating policies, each safe stakeholder hereby disclaims any and all warranties, both express and implied, including any implied warranties of merchantability, fitness for a particular purpose, non-infringement, quiet enjoyment, accuracy of information provided with respect to the subject matter of these operating policies. SAFE-BioPharma-Biopharma further disclaims any and all warranties, both express and implied, that the use of the safe services will affect in any manner the legal recognition or enforceability of a digital record.

3.8 Suspension and Termination of SAFE-BioPharma Stakeholders

While the details of the causes and procedures relating to the Suspension and Termination of SAFE-BioPharma Stakeholders are set forth in Section 3.4 of the Document SAFE-BioPharma Accreditation Process, the following principles apply:

1. SAFE-BioPharma Issuers and SAFE-BioPharma Members may voluntarily terminate their participation in the SAFE-BioPharma System with 60 days notice;
2. SAFE-BioPharma may Suspend and Terminate SAFE-BioPharma Issuers and SAFE-BioPharma Members for cause;
3. SAFE-BioPharma may, under certain circumstances, cause a SAFE-BioPharma Issuer to revoke or suspend a SAFE-BioPharma Member. SAFE-BioPharma Issuers and SAFE-BioPharma Members are otherwise free to establish the conditions for terminating the bilateral agreements that they enter into under these Operating Policies.

4. Fees and Charges

4.1 Determination and Adjustment of Fees

The SAFE-BioPharma Board shall determine the fees applicable to SAFE-BioPharma Members and SAFE-BioPharma Issuers. The SAFE-BioPharma Board may adjust fees annually subject to a 60 day notice period.

4.2 SAFE-BioPharma Member Fees

Member Fees shall be set by SAFE-BioPharma and shall be provided to Members on an annual basis.

4.3 SAFE-BioPharma Issuer Fees

Issuer Fees shall be set by SAFE-BioPharma and shall be provided to Issuers on an annual basis.

4.4 Charges for Additional Services

SAFE-BioPharma maintains the right to collect service charges for the use of additional services available to Members and Issuers. These charges are additional to the base fees required for SAFE-BioPharma Members and SAFE-BioPharma Issuers.