

	<b>Carl Zeiss Meditec, Inc.</b>
Approval Date: 12/1/2018 Effective Date: 12/1/2018 Revision Date: 12/1/2018	Policy and Guidelines: SOPP-001 Carl Zeiss Meditec, Inc. Code of Conduct

## 1.0 General

Carl Zeiss Meditec, Inc. (CZMI) is committed to upholding the highest ethical standards in its business practices. These standards are driven by the principles of the Carl Zeiss (CZ) Group, requirements of federal and state regulations, and industry standards. This policy is based on legal and ethical guidelines governing CZMI's interactions, including the CZ Code of Conduct, the AdvaMed Code of Ethics on Interactions with Health Care Professionals, and applicable laws including the U.S. Anti-Kickback Statute and the Foreign Corrupt Practices Act (FCPA). It also generally defines additional specific policies in order to meet compliance requirements of state laws when they are more stringent than the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

In all cases, employees should refer to the referenced documents for a detailed understanding of the Code of Conduct.

## 2.0 References

### **Code of Conduct for the Carl Zeiss Group: CM.01**

[http://zeissnet.zeiss.org/C1257267002A2055/vwByDocID/7398A79301153ABD88258291007B200A/\\$File/CZ\\_Group\\_Code\\_of\\_Conduct\\_CSOP\\_CM.01\\_April\\_2018.pdf](http://zeissnet.zeiss.org/C1257267002A2055/vwByDocID/7398A79301153ABD88258291007B200A/$File/CZ_Group_Code_of_Conduct_CSOP_CM.01_April_2018.pdf)

### **AdvaMed Code of Ethics on Interactions with Health Care Professionals:**

[https://www.advamed.org/sites/default/files/resource/112\\_112\\_code\\_of\\_ethics\\_0.pdf](https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf)

### **U.S. Department of Health and Human Services Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers (which also applies to device manufacturers)**

<http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

### **U.S. Anti-Kickback Statute**

<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXI.htm>

### **U.S. FOREIGN CORRUPT PRACTICES ACT (FCPA)**

<https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf>

### **CA - HEALTH AND SAFETY CODE SECTION 119400-119402**

[https://leginfo.legislature.ca.gov/faces/codes\\_displayText.xhtml?lawCode=HSC&division=104.&title=&part=15.&chapter=8.&article=](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=15.&chapter=8.&article=)

### **California Comprehensive Compliance Program and Declaration of Compliance MA – 105 CMR 970.000 – Final Pharmaceutical & Medical Device Manufacturer Conduct Regulations**

<http://www.mass.gov/eohhs/docs/dph/regs/105cmr970.pdf>

### **NV- AB 128, Statutes of Nevada Chapter 409**

[http://bop.nv.gov/uploadedFiles/bopnvgov/content/Resources/ALL/Annual\\_Certification\\_Manufacturers\\_Wholesalers.pdf](http://bop.nv.gov/uploadedFiles/bopnvgov/content/Resources/ALL/Annual_Certification_Manufacturers_Wholesalers.pdf)

**The Vermont Statute: Title 18: Health, Chapter 91: PRESCRIPTION DRUG COST CONTAINMENT, 18 V.S.A. § 4632.**

<https://legislature.vermont.gov/statutes/section/18/091/04632>

**Acceptance of Gifts Policy HR31**

[http://zeissnet.zeiss.org/C1257267002A2055/vwByDocID/A10083B55302B6D0882580DB005D4D62/\\$File/31-Acceptance\\_of\\_Gifts-April\\_2017-FINAL.pdf](http://zeissnet.zeiss.org/C1257267002A2055/vwByDocID/A10083B55302B6D0882580DB005D4D62/$File/31-Acceptance_of_Gifts-April_2017-FINAL.pdf)

### 3.0 Definitions

**AdvaMed:** Advanced Medical Technology Association is an association of companies who produce medical devices, diagnostic products and health information systems who advocate for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. AdvaMed produces the standard for business' code of ethics on interactions with health care professionals in their industry.

**HCP:** Health Care Professional. Individuals (whether clinical or non-clinical, including without limitation, physicians, physician assistants, nurses, technicians, purchasing managers, and office staff) and entities (including, without limitation, hospitals and group purchasing organizations) involved in the provision of health care services and/or items to patients, which directly or indirectly purchase, lease, use, prescribe, or recommend or arrange for the purchase, lease, use, or prescription, of any CZMI products or services.

**CZMI:** Carl Zeiss Meditec, Inc.

### 4.0 Policy

#### 4.1 Principles

This Code of Conduct is limited to the formulation of basic behavioral requirements in our business activities and refers to more extensive documents and information for sensitive and legally regulated areas. Additionally, no statement can cover all situations that might arise in the course of business. Accordingly, CZMI management and employees are expected to comply with this policy and the referred references, using their best judgment, in those cases not specifically addressed.

At CZMI, management and employees are expected to adhere to the Code of Conduct for the Carl Zeiss Group in addition to complying with the laws and regulations of the United States Federal Government, individual states, and other countries where CZMI conducts business.

If a conflict is found between CZMI Policies and the Code of Conduct for the Carl Zeiss Group, then the stricter policy shall be followed.

#### 4.2 Interaction with employees and business partners

In addition to the policies on interactions with employees and business partners stated in the Code of Conduct for the Carl Zeiss Group, employees at CZMI must adhere to local, State and Federal regulations.

##### 4.2.1 U.S. Federal Laws and Regulations

The U.S. Physician Payment Sunshine Act (now referred to as "Open Payments"), a provision of the Patient Protection and Affordable Care Act, is a U.S. federal law that requires medical device manufacturers to track and report payments and transfers of value provided to U.S. licensed physicians and teaching hospitals. If CZMI makes a "payment or transfer

of value” to a U.S. physician or teaching hospital (for example, a meal, travel, lodging, etc.), we must provide information about the interaction to the U.S. government. The U.S. Sunshine Act applies to interactions with U.S. licensed physicians regardless of the country where those interactions occur.

CZMI must capture and report payments and transfers of value, including expenses such as travel, lodging and meals, consulting payments, royalty payments and licensing fees, research and clinical-trial related expenditures, educational items such as textbooks and journal reprints, training and education expenses, educational and research grants, and charitable donations, among others. CZMI must also report the value of demonstration products left at one site for more than 90 days. However, it is CZMI’s policy to limit product demonstrations to no more than 90 days.

Companies must submit an annual report regarding interactions with U.S. physicians and teaching hospitals to the U.S. federal government no later than March 31 of each year. For more information about the Sunshine Act, refer to the AMA website, AdvaMed website and the Center for Medicare and Medicaid Services website.

#### **4.2.1.1 U.S. Anti-Kickback Statute**

A key law that governs CZMI’s interactions and relationships with HCPs is the U.S. Anti-Kickback Statute. The U.S. Anti-Kickback Statute and its implementing regulations provide that anyone who knowingly and willfully offers, gives, solicits, or receives anything of value to influence or reward the ordering, purchasing or referring of federal or state health care program business can be charged with a felony. The U.S. Anti-Kickback Statute prohibits CZMI from providing payments, gifts, or other things of value to HCPs that are intended to induce someone to order, purchase, use, refer (or recommend or arrange for the order, purchase, use, or referral) of a CZMI product when that product is reimbursable by Medicare, Medicaid, or other governmental health care program. A key aspect of this law, commonly known as the “One Purpose Test,” provides that even if there are other legitimate purposes for a transaction, if even one purpose of the transaction is to induce ordering, purchasing, using, or referring of a CZMI product, the transaction could be construed as an illegal kickback. In order to ensure compliance with local, state and federal regulations, including the U.S. Anti-Kickback Statute, CZMI has adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

#### **4.2.1.2 Federal Foreign Corrupt Practices Act (FCPA)**

In addition, CZMI complies with the Federal Foreign Corrupt Practices Act (FCPA). As such, all Directors, officers, employees, representatives, agents, and business partners (around the world) are prohibited from offering, authorizing, promising, or providing anything of value, to any non-U.S. government official, political party, party official, or candidate for foreign political office, for the purpose of influencing the non-U.S. official or party to assist the company in obtaining or retaining business or securing an improper business advantage. The FCPA requires that CZMI implement processes with appropriate controls to ensure compliance.

Some States have implemented specific regulations governing interactions with Health Care Professionals that are licensed in those states, regardless of where the interactions occur. In some cases, the regulations are stricter than the Code of Conduct for the Carl Zeiss Group and the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

#### **4.2.1.3 U.S. State Laws and Regulations**

Some states, such as California, Massachusetts and Vermont, have imposed limits on how medical device companies can interact with health care providers who are licensed to practice by these states. These state regulations will remain in effect alongside the U.S. Physician Payment Sunshine Act. In addition, some states such as Massachusetts have state anti-kickback laws which are broader than the U.S. Anti-Kickback Statute.

California requires medical device manufacturers to make available by request a copy of our comprehensive compliance program and an annual certification as to compliance. We make this available by request via a Toll-Free Number: (877) 705-4029.

Both Massachusetts and Vermont require medical device manufacturers to submit an annual report detailing a wide variety of financial interactions with certain physicians and other health care providers licensed by those states. Similar to other medical device manufacturers who do business in those jurisdictions, CZMI may be required by law to report many types of direct and indirect payments and other transfers of value to physicians and other health care providers licensed by those jurisdictions. This generally includes the name of the contracting party, the purpose of the payment, the amount and nature of any payments made, and possibly other information about the payment.

Massachusetts and Vermont also require medical device manufacturers to comply with separate marketing codes of conduct, which regulate how employees of these companies can interact with health care providers licensed by these states. More information is made available by accessing the [Massachusetts requirements](#) and the [Vermont requirements](#).

Nevada requires device manufacturers to adopt a marketing code of conduct and to certify that an annual audit to monitor compliance with the marketing code of conduct has been done. CZMI does so by adopting the AdvaMed Code of Ethics on Interactions with Health Care Professionals without modification and annually certify that they conduct annual audits to monitor compliance.

### **4.3 Fair Competition**

We are dedicated to ethical, fair and vigorous competition. We will sell CZMI products and services based on their merit, superior quality, functionality and competitive pricing. We will make independent pricing and marketing decisions and will not improperly cooperate or coordinate our activities with our competitors. We will not offer or solicit improper payments or gratuities in connection with the purchase of goods or services for CZMI or the sales of its products or services, nor will we engage or assist in unlawful boycotts of particular customers.

### **4.4 Granting and Accepting Benefits**

No personal benefits may be requested, accepted, offered or granted with the intention of receiving preferential treatment in the initiation, awarding or processing of an order. Under no circumstances may gifts be given or accepted. Exceptions are granted only for nominal gifts for a specific occasion or advertising gifts and for gifts that correspond to standard behavior and courtesy in a country and which comply with legal stipulations. Particular restraint is required of public officials, including those from outside Germany. Even the open-ended loan or acceptance of products or other items may assume the appearance of a forbidden gift or the acceptance or granting of benefits. Invitations from or through business partners which are unrelated to business calls, unusual or disproportionate shall require internal approval. If an employee is confronted with an offer of or request for personal benefits, this must be reported to his/her superior immediately.

At CZMI, management and employees are expected to adhere to the Code of Conduct for the Carl Zeiss Group in addition to complying with the laws and regulations of the United States Federal Government and the States and other countries where CZMI conducts business. In order to ensure compliance with local, State and Federal regulations, CZMI has adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals and specific additional policies listed under section 3.2 of this policy in addition to the policies listed in the Code of Conduct for the Carl Zeiss Group.

The Company's Grants Program provides funding to support appropriate charitable activities, educational activities and research related to disease states, conditions and treatment for which the Company's products are used. Any funding provided by the Company that will benefit a Customer or organization closely affiliated with a Customer must satisfy the criteria outlined in the Grants Program Charter and Policy, and be approved in advance by the Grants Committee.

Charitable donations to organizations/institutions whose aims do not correspond to the mission statement of Carl Zeiss as set out in the Code of Conduct are prohibited. Charitable donations to individuals, consultants, or individuals that provide professional services to CZMI are not permitted. Donations to political, religious and sectarian establishments – even if not for profit – are strictly prohibited.

#### **4.5 Handling of Company Property**

Each employee is obligated to treat all operating equipment (machines and tools in particular) as well as all information and communication systems carefully and in accordance with their intended purpose.

All employees will take appropriate actions to protect the Company's assets and ensure their efficient use for legitimate business purposes.

#### **4.6 Protecting, Disclosing & Receiving Confidential Information**

You have a duty to protect Company information. Company confidential information includes a wide range of non-public information including but not limited to financial and cost data, business plans and strategies, operating reports, pricing information, marketing and sales data, business partner information, research and development (R&D), trade secrets, proprietary information, technical information and source code, personnel records, and organization charts. Appropriate security measures to protect company information from improper disclosure should be taken in accordance with applicable Company IT, Security, and Legal policies and guidelines.

Disclosure of company information may be made only by those authorized to do so and in compliance with Company policies.

This also applies to protecting our intellectual property from the knowledge of or unauthorized access by third parties. Acceptance of confidential information from others must also be handled with care and in compliance with Company policies.

#### **4.7 Ban on Insider Trading**

Insider trading laws prohibit the use of insider information to gain direct or indirect personal benefits through the purchase or sale of securities as well as the unauthorized dissemination of such information. Insider information refers to all facts that are not generally known which refer to the issue of securities and which can considerably influence the value of these securities if made public, i.e. information that an investor would consider important in his/her decision to buy or sell. Examples include: information on planned acquisitions, strategic alliances, financial results, new products, problems with products or important agreements.

Prohibited insider trading can have considerable criminal and civil consequences for both the employee and the company.

#### **4.8 Avoiding Conflicts of Interest / Private Activities**

To avoid any conflicts between private and corporate interests, any employee who intends to undergo the following must inform his/her superior or the HR department responsible and must obtain permission:

- undertake an additional position in another company
- perform paid secondary activities
- perform an entrepreneurial activity

This also applies to the performance of unpaid secondary activities, if doing so may lead to conflicts of interest.

#### **4.9 Anti-discrimination**

All employees and business partners have the right to fair, polite and respectful treatment by superiors, colleagues and employees. Nobody may be harassed or discriminated against based on race, skin color, nationality, ancestry, gender, sexual identity, religion, world view, political orientation, age, physique or appearance.

Each employee is obligated to respect the personal sphere of other employees. Sexual harassment and mobbing are prohibited.

#### ***4.10 Adherence to Import and Export Controls and Customs Regulations***

Carl Zeiss is a global company. Within the scope of its international activities, it must comply with regulations which limit the free movement of goods. Various national and international laws or embargoes limit or forbid the import, export or domestic trade of goods, technologies and services, as well as monetary transactions and the movement of capital. The limitations and bans can be due to the nature of the goods, the country of origin, the country in which the goods are to be used, or who the business partner is.

National and international export control regulations are particularly important. Each employee must comply with these control regulations if goods or services are purchased, arranged, manufactured or put into service, or if technologies are transferred or accepted.

In addition, the applicable version of the regulations on Customs and export control must be adhered to.

#### ***4.11 Occupational Health and Safety***

All employees are expected to comply with the safety regulations and to be aware of hazards and safety-related activities. This applies to all hazards that could occur at our employees' workstations or during the use of our products. All detected accidents, hazards and exposures which are considered possible as well as near misses must be immediately reported to the superior responsible.

The management of the business units is required to establish and monitor a safety organization. Each superior is responsible for the protection of his/her employees and must provide instruction, training and supervision. In order to determine and evaluate risks to and strain on individuals, all management personnel are required to carry out regular risk assessments which identify and evaluate risks to individuals and their health at their workstations. This includes the organization of occupational health care.

At CZMI, management and employees are also expected to comply with the Code of Conduct for the Carl Zeiss Group in addition to complying with the laws and regulations of the United States Federal Government and the States and other countries where CZMI conducts business.

#### ***4.12 Product Safety***

CZMI is committed to producing products that are safe and effective. In developing and manufacturing medical devices and other products, CZMI has established and will comply with standards that meet or exceed regulations promulgated by the Food and Drug Administration or other applicable laws and regulations. In manufacturing its products, CZMI will comply with all applicable laws and regulations, including those relating to the environment and occupational health and safety.

#### ***4.13 Environmental Protection***

CZMI is committed to responsible environmental practices throughout our business. Our environmental policies and practices include programs designed to increase the energy efficiency of our operations, reduce waste, and protect the environment.

#### ***4.14 Data Privacy, Protection, Handling Information & Documentation***

CZMI is committed to protecting the personally identifiable information of its employees, customers, suppliers, and other business partners. Personally identifiable information includes data related to a person who can be identified or

located by that data. In order to create an environment of trust and to comply with applicable laws, employees are required to follow CZMI privacy and security policies and data protection practices in using online and offline systems, processes, products, and services that involve the use, storage, or transmission of any personally identifiable information.

CZMI is also committed to protecting legitimate privacy interests of its employees and the workplace. While seeking to maintain employee privacy, however, CZMI reserves the right to monitor use of company property, premises, and resources (for example, office sites, computers, email, phones, propriety information, etc.) in accordance with applicable laws and as necessary to protect the interests of the company.

While CZMI is not a HIPAA Covered Entity (except for certain portions of our group health plan), we recognize the impact that HIPAA privacy and security regulations have on our customers. CZMI remains committed to interacting with our customers and their patients as responsible professionals who are dedicated to maintaining the privacy of information that we receive on the job, consistent with applicable law, regulations and CZMI policies. Targeted employees in the marketing and sales organization will be required to complete HIPAA Compliance training within 30 days of their hire date.

#### **4.15 Behavior Towards Authorities**

CZMI endeavors to maintain an open and cooperative relationship with all responsible authorities. If authorities follow up on violations of applicable law, the processes involved follow specific rules.

No employee is allowed to destroy, remove or alter printed or electronic company documents associated with a judicial, official or civil investigation or lawsuit.

#### **4.16 Managing Suppliers**

Properly managing relationships with suppliers is vital to the success of CZMI worldwide operations. We are required to deal with suppliers in a professional and fair manner, to document properly all transactions, and to manage supplier relationships in accordance with the best interests of CZMI and in accordance with applicable internal policies and procedures. CZMI is required to document all supplier relationships in appropriate written contracts where applicable.

#### **4.17 Compliance with the Code of Conduct and monitoring**

Any interpretation of the provisions of this Code, and interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: CZMI employees shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of CZMI-supplied products.

The Principles apply to all CZMI employees, including, temporary agency personnel, independent contractors, independent sales representatives, and distributor representatives. All CZMI employees are responsible for complying with any state law restrictions on interactions with Health Care Professionals (e.g., California, Massachusetts, Nevada, and Vermont), and any state and federal government ethics laws that apply to interactions with government employees.

To ensure Compliance at CZMI, four processes take place;

- Prevention – through training and organizational measures;
- Detection – through encouraging CZMI employees and others to report known or suspected instances of noncompliance to the appropriate CZMI personnel, general auditing, and examination of isolated incidents;
- Appropriate response – through evaluation of misconduct, taking appropriate and consistent disciplinary action in response to confirmed misconduct, and implementing necessary and appropriate corrective and preventive actions in response to confirmed misconduct;
- Compliance Reporting and Certification.

#### **4.17.1 Preventive**

The CZMI training program for the CZMI Code of Conduct and HCP Compliance is a multi-phased program to ensure that all CZMI employees receive basic training. The “New Employee Orientation Program” includes the CZMI Code of Conduct and training will be completed within 30 days of hire date. Additional job specific training requirements for employees are defined based on the employee’s job description.

Additional training on the AdvaMed Code of Ethics on Interactions with Health Care Professionals and applicable federal and state laws that regulate interactions with HCPs is provided to all Sales and Marketing employees. Additional product-specific training is provided to Marketing and Sales personnel to ensure that they can provide accurate, up-to-date information on CZMI Products to HCPs. All employees in the marketing and sales organization will complete HCP Compliance training within 30 days of their hire date. Recertification training for all CZMI sales and marketing on the CZMI Code of Conduct and the HCP Compliance training will be completed on an annual basis.

Materials used in the training will be reviewed and updated, as regulations change, to reflect changes to the CZMI Code of Conduct and applicable laws and regulations impacting the Code of Conduct and federal and state HCP Compliance laws. Maintaining and monitoring employees’ current training status to the CZMI training program is the responsibility of the employees’ managers and the employees themselves.

In addition to direct employees, CZMI employs distributors and agents to support the CZMI sales activities in various states. These agents and distributors are responsible for defining and maintaining their own training programs and certifying to the CZMI Compliance Officer that they are compliant with CZMI’s Code of and federal and state laws and regulations in the areas that they sell, distribute or service CZMI products.

Compliance to the CZMI Code of Conduct and HCP Compliance Process is overseen by the CZMI Compliance Officer with the support of the CZMI President and his executive management team. CZMI Employees are encouraged to escalate potential noncompliance events to their direct management.

#### **4.17.2 Detection**

Monitoring compliance with the CZMI Code of Conduct will be conducted through auditing activities that will occur at a minimum of once per year, in accordance with the CZMI Internal Audit Schedule. In addition, to comply with laws in particular states that restrict interactions with HCPs licensed in those states (e.g., Massachusetts and Nevada) and support certifications that the CZMI Compliance Officer must submit to government agencies, CZMI will conduct annual audits to review and assess the Company’s compliance with those particular laws.

Noncompliance discovered during Internal Audits will be handled following the CZMI Internal Audit and CAPA processes.

In addition to regular auditing and monitoring, employees are responsible for reporting known or suspected compliance violations to their immediate supervisor or the CZMI Compliance Officer, or to confidentially report known or suspected violations by calling CZMI’s Compliance Hotline.

CZMI Compliance Officer Phone:	(925) 557- 4801
CZMI Compliance Officer Email:	Mareike.Hinck@zeiss.com
CZMI Compliance Hotline:	(877) 705-4029

Any and all alleged violations of the CZMI Code of Conduct or other compliance policies shall be investigated. The investigation will be overseen by the CZMI Compliance Officer. The investigation results will be reviewed and assessed by the CZMI Compliance Officer. The investigation results will be documented and for confirmed compliance violations, the appropriate corrective action will be taken. The extent of the corrective action will be based on the severity of the violation. If the CZMI Compliance Officer determines that a policy violation also resulted in a violation of applicable law or regulation, the Compliance Officer will determine whether external authorities should be made aware of the violation.

### **4.17.3 Appropriate Response**

The Company is committed to taking consistent and appropriate action to address inappropriate conduct and to deter future violations. In addition, adherence to the CZMI Code of Conduct and other compliance policies will be a factor in all applicable employee performance evaluations. Disciplinary action for noncompliance will follow the CZMI Progressive Discipline Process. However, exceptions or deviations from the normal procedure may occur whenever the Company deems that circumstances warrant skipping one or more steps in the process and may include a broad range of disciplinary measures, up to and including termination of employment.

### **4.17.4 Compliance Reporting and Certification**

Annual compliance reporting and/or certification will be based on federal and state laws and regulations. The CZMI Compliance Officer will assess new or changes to existing laws and regulations and oversee activities undertaken to comply with such laws and regulations.

The CZMI Compliance Officer will annually review the internal audit findings on CZMI Code of Conduct and any investigations or corrections that occurred during the course of the year. The CZMI Compliance Officer will certify, register or otherwise notify the required states of the status of the CZMI Code of Conduct and HCP Compliance.

CZMI will comply with state required reporting/disclosure requirements, including annual audit and certification requirements. A copy of the CZMI Comprehensive Compliance Program and its annual written declaration of compliance with the program can be requested by calling: CZMI's Compliance Toll Free Number at (877) 705-4029.

## **5.0 Responsibilities**

The President is responsible for:

Establishing a CZMI Code of Conduct, providing adequate resources to maintain compliance to the CZMI Code of Conduct and associated federal and state laws, and assigning the Compliance Officer role within CZMI.

The CZMI Compliance Officer is responsible for:

Overseeing and certifying compliance with the Carl Zeiss Group Code of Conduct, CZMI's Code of Conduct, the AdvaMed Code of Ethics on Interactions with Health Care Professionals, and all applicable federal and state laws that apply to HCP compliance. The Compliance Officer is responsible for reporting instances of non-compliance to the appropriate internal and external authorities. In addition, the CZMI Compliance Officer is responsible for defining the content of the CZMI Code of Content and ensuring that the responsibilities for implementation of the CZMI Code of Conduct and HCP Compliance process are defined. The CZMI Compliance Officer is responsible for overseeing compliance training content and ensuring that it is current.

CZMI Human Resources (CZMI HR) is responsible for:

The Coordination and tracking of new employee training and annual re-certification training for the CZMI Code of Conduct and HCP Compliance training. Additionally, CZMI HR in conjunction with the CZMI Compliance Officer is responsible for defining, implementing and overseeing policies and procedures for investigation of alleged noncompliance, the management structure for escalation of alleged noncompliance within CZMI, and employee disciplinary action as a result of confirmed noncompliance in association with the CZMI Code of Conduct.

CZMI Employees are responsible for:

Training and maintaining certification to, and complying with the CZMI Coded of Conduct and reporting potential compliance violations to their management or to the CZMI Compliance Hotline. As well as supporting investigations into alleged violations and following all applicable federal and state laws.

Changes to this policy shall be approved by management personnel responsible for the following functions:

- CZMI President
- CZMI Compliance Officer