



## POSITION DESCRIPTION

|   |   |
|---|---|
| <b>Position Title:</b>                    | Manager, Regulatory Affairs & Compliance (Life Sciences & Research) |
| <b>Cluster / Business Unit / Division</b> | Chief Operating Officer Group                                       |
| <b>Section or Unit:</b>                   | Regulatory and Governance   |
| <b>Classification:</b>                    | Band 7  |
| <b>Job Family:</b>                        | Compliance & Regulation   |
| <b>Position Description Number:</b>       | PD-2463   |
| <b>Work Contract Type:</b>                | Professional  |
| <b>STEMM/NON-STEMM:</b>                   | NON-STEMM   |

---

### POSITION PURPOSE

The primary objective of the role is to provide assurance to the CEO that an effective process for ensuring ANSTO complies with key regulatory requirements for all ANSTO regulators. The role also facilitates ANSTO's interactions with government agencies, departments, and regulators on regulatory matters. This role operates as part of the Governance and Regulatory team and will contribute to good governance across ANSTO.

A specific focus of the role will be to partner with business stakeholders to lead and coordinate ANSTO's engagement with the TGA. This role would also maintain Executive Officer responsibility for various research committees that ANSTO operates. The Executive Officer will liaise with key stakeholders on all matters pertaining to academic research, including Animal Ethics committees.

### ORGANISATIONAL ENVIRONMENT

ANSTO leverages great science to deliver big outcomes. We partner with scientists and engineers and apply new technologies to provide real-world benefits. Our work improves human health, saves lives, builds our industries and protects the environment. ANSTO is the home of Australia's most significant landmark and national infrastructure for research. Thousands of scientists from industry and academia benefit from gaining access to state-of-the-art instruments every year.

The Chief Operating Officer Group brings together several Corporate Services Functions from across ANSTO; creating greater synergies across operational areas of our organisation, and more streamlined interfaces with the Department of Industry, Science, Energy and Resources and other Federal agencies.

- Finance and Operational Services
- Government and International Affairs
- Legal Services
- People, Performance and Capability
- Regulatory and Governance
- Corporate Affairs
- Capital Program Management Office

### ACCOUNTABILITIES & RESPONSIBILITIES

#### Key Accountabilities

- Design, implement, and continuously improve a governance model for ANSTO that supports compliance with relevant regulatory obligations.
- Provide advice on interpretation and application of regulatory obligations to ANSTO's operational activities (for example, legislations, regulations, licence/permit conditions) to ensure ANSTO obtains

appropriate licences and remains compliant with any licence or permit conditions across the organisation.

- Maintain an accurate and up-to-date compliance register in alignment with ANSTO's enterprise-wide compliance framework and advise on regulatory change management activities.
- Work closely with stakeholders to ensure oversight of all regulatory matters.
- Facilitate and initiate internal and external exchange of information and correspondence on key regulatory issues, including on post-event correspondence.
- Co-ordinate and facilitate reporting by licensing and regulatory officers, keep abreast of regulatory updates and communicate that information internally.
- Develop and oversee a centralised register of regulatory correspondence relating to Office of Gene Technology related matters.
- Work closely with business units to support their preparation of regulatory submissions.
- Establish and maintain an effective and collaborative working relationship with external regulators.
- Perform the secretariat function of ANSTO's various research committees, including to perform tasks required to manage:
  - the relationship between ANSTO and its regulators for animal research activities in NSW and VIC; and
  - all administrative aspects of the ANSTO Animal Care and Ethics Committee (**ACEC**) and the Australian Synchrotron Animal Ethics Committee (**AS-AEC**) including minuting, provide relevant contributions to ANSTO's reporting requirements under applicable international frameworks.
- Identify areas of regulatory and compliance risk and support continuous improvement initiatives.
- Develop and improve compliance maturity across ANSTO through the centralisation of the regulatory functions in accordance with ANSTO's Compliance Framework (including to drive continuous improvement in the quality of regulatory submissions).
- Assist in the maintenance of Regulatory Inspections, Submissions, Lessons Learnt and notifications as a basis for compliance metrics for ANSTO.
- Assist in the maintenance of a regulatory and compliance key events calendar.
- Assist with the prioritisation of regulatory submissions based on the whole of ANSTO approach by embedding a forecast of regulatory submissions into key business processes.
- Undertake additional duties as required and during periods of leave of other staff within the Regulatory and Governance Team.

### **Decision Making**

- The position works within ANSTO's Compliance Framework and delegations of authority matrix. Within this framework, the position has some independence in determining how to achieve objectives, including deciding on methods and approaches and operations.
- Provides independent advice and assurance to ANSTO's CEO, COO, and business divisions with respect to compliance matters.
- The position assists to coordinate responses to internal inquiries and prepares responses for external enquiries.

### **Key Challenges**

- Providing accurate, clear and authoritative advice and information on regulatory and compliance matters to internal and external stakeholders;
- Obtaining current regulatory compliance information from key stakeholders across the organisation;
- Ensuring reporting deadlines are met by interpreting licensing and regulatory requirements, facilitating timely reporting, and meeting the tight time frames required for specific reports.

## KEY RELATIONSHIPS

| Who  | Purpose  |
|--|--|
| <b>Internal</b>  |  |
| Chief Executive Officer, ANSTO Board and Company Secretary                               | <ul style="list-style-type: none"> <li>• Provide independent advice on regulatory compliance;</li> <li>• Provide support to maintain the professional image of the CEO, COO and ANSTO.</li> </ul>  |
| Chief Nuclear Officer  | <ul style="list-style-type: none"> <li>• Assist with the coordination of all responses to parliamentary questions and major licensing decisions for referral to the CEO.</li> <li>• Engage on strategic projects for ANSTO and ARPANSA</li> </ul>  |
| General Manager, Regulatory & Governance and the Senior Manager, Regulatory & Compliance | <ul style="list-style-type: none"> <li>• Assist the Senior Manager, Regulatory &amp; Compliance and General Manager, Regulatory &amp; Governance to provide independent advice on regulatory affairs and compliance matters and dealing with all regulators.</li> </ul>  |
| Work area team members   | <ul style="list-style-type: none"> <li>• Collaborate and share accountability.</li> </ul>  |
| Regulatory role holders  | <ul style="list-style-type: none"> <li>• Coordinate and facilitate regulatory reporting in accordance with the Compliance Framework.</li> <li>• Communicate regulatory updates.</li> </ul>   |
| Safety Reliability and Assurance   | <ul style="list-style-type: none"> <li>• Assist with the maintenance of the forecast of regulatory submissions.</li> <li>• Assist in ensuring effective regulatory submissions and provide assurance and advice regarding maintenance of plans and arrangements.</li> </ul>  |
| ACEC and AS-AEC Chairperson  | <ul style="list-style-type: none"> <li>• Obtain approvals pertaining to AEC submissions</li> <li>• Receive guidance and direction from relevant regulatory subject matter experts on research matters</li> <li>• Report on issues</li> </ul>   |
| Vivarium Facility Manager/IMBL Animal Facility Manager                                   | <ul style="list-style-type: none"> <li>• Provide expert advice and analysis on a full range of matters</li> <li>• Provide copies of all approvals</li> <li>• Collaborate and manage matters relating to compliance</li> <li>• Coordinate inspections of animal holding facilities</li> <li>• Report on issues</li> </ul> |
| ANSTO Researchers/Animal users   | <ul style="list-style-type: none"> <li>• Provide expert advice and analysis on a full range of matters</li> <li>• Provide feedback and outcomes on AEC submissions</li> <li>• Report on issues</li> <li>• Follow-up actions relating to animal ethics</li> </ul>   |
| CEO Delegate for the ACEC (Lucas Heights)  | <ul style="list-style-type: none"> <li>• Obtain approvals pertaining to AEC matters</li> <li>• Report on issues</li> <li>• Complete mandatory/annual reports</li> </ul>  |
| Licence Nominee (Australian Synchrotron)   | <ul style="list-style-type: none"> <li>• Obtain approvals pertaining to AEC matters</li> <li>• Report on issues</li> <li>• Manage matters relating to compliance in alignment with ANSTO's Compliance Framework</li> <li>• Complete mandatory/annual reports</li> </ul>  |
| <b>External</b>  |  |
| Regulating and Licensing Agencies  | <ul style="list-style-type: none"> <li>• Establish and maintain an effective and collaborative working relationship with external regulators.</li> </ul>   |
| NSW Department of Primary Industries   | <ul style="list-style-type: none"> <li>• Report on issues</li> <li>• Obtain licence in accordance with NSW Regulations</li> <li>• Provide mandatory reports</li> <li>• Coordinate mandatory audits</li> </ul>  |

|                                   |   |
|-----------------------------------|---|
| Animal Welfare Victoria           | <ul style="list-style-type: none"> <li>• Report on issues</li> <li>• Obtain licence in accordance with VIC Regulations</li> <li>• Provide mandatory reports</li> <li>• Coordinate mandatory audits</li> </ul>   |
| External AEC members              | <ul style="list-style-type: none"> <li>• Coordinate AEC committee members</li> </ul>  |
| External Animal Ethics Committees | <ul style="list-style-type: none"> <li>• Collaborate and manage AEC approvals between institutes</li> <li>• Collaborate and develop agreements between institutes</li> <li>• Report on animal ethics issues</li> <li>• Report on compliance issues</li> </ul> |
| External researchers/Animal users | <ul style="list-style-type: none"> <li>• Provide feedback and outcomes on AEC submissions</li> <li>• Report on issues</li> <li>• Follow-up actions relating to animal ethics</li> </ul>   |

## POSITION DIMENSIONS

### Staff Data

|                  |  |
|------------------|--|
| Reporting Line   | Reports to the Senior Manager, Regulatory & Compliance and Chair ACEC/AS-AEC |
| Direct Reports   | Nil  |
| Indirect Reports | ACEC and AS-AEC Committee Members  |

### Special / Physical Requirements

|                         |  |
|-------------------------|--|
| Location:               | Working in different areas of designated ANSTO's site/campuses as required. The role could be based at either Lucas Heights (Sydney) or Clayton (Melbourne).   |
| Travel:                 | May be required travel to ANSTO sites from time to time. Frequent travel interstate.   |
| Physical:               | Office based physical requirements (sitting, standing, minimal manual handling, movement around office and site, extended hours working at computer).<br>Public speaking.  |
| Radiation areas:        | May be required to work in radiation areas under tightly regulated conditions.<br>Perform duties in an area where radioactive materials are handled under tightly controlled safety conditions.<br>Perform duties with and in an area where hazardous chemicals or materials are handled under tightly controlled safety conditions. |
| Hours:                  | Willingness to work extended and varied hours based on operational requirements.   |
| Clearance requirements: | Satisfy ANSTO Security and Medical clearance requirements.<br>Will be required to obtain and maintain National Security Clearance at Negative Vetting Level 1 and may be required to obtain and maintain appropriate National Security Clearance at Negative Vetting Level 2 (Top Secret).   |

### Workplace Health & Safety

|  |  |
|--|--|
| Specific role/s as specified in <a href="#">AP-2362</a> of the ANSTO WHS Management System | All Workers<br>Managers / Leaders / Supervisors<br>Other specialised roles identified within the guideline a position holder may be allocated to in the course of their duties |
|--|--|

## ORGANISATIONAL CHART

On file

## KNOWLEDGE, SKILLS AND EXPERIENCE

1. Degree or higher in relevant science, legal or other discipline.
2. Significant experience within ANSTO's regulatory environment, or in a highly regulated environment.
3. Sound understanding of ARPANS Act, Regulations and guidance and associated regulatory requirements.
4. Sound understanding of applicable Work Health and Safety and Environmental regulatory requirements.
5. Developing understanding of research and animal ethics regulatory requirements
6. Strong ability to influence at all levels of the organisation and with external stakeholders.
7. Employment of effective time management skills.
8. Strong verbal, written and report writing communication skills.
9. Experience and demonstrated achievement in committee servicing and support
10. Well-developed oral and written communication skills, careful attention to detail
11. And demonstrated experience in writing accurate and concise minutes; preparing careful responses reflecting committee decisions on complex issues; preparing advisory notes; dealing with a wide range of people and conveying complex and confidential information in a sensitive yet clear manner
12. Experience in providing high level advice to stakeholders, involving the ability to interpret policies and regulatory requirements
13. Experience in providing compliance in a highly regulated environment and willingness to develop an understanding of quality management systems as they relate to ANSTO's operational activities
14. The ability to recognise possible points of concern or contention, and to assess how these can be most effectively handled, including the ability to exercise mature judgement and discretion when dealing with confidential and sensitive issues
15. Ability to prioritise and carry out a diverse range of competing tasks to a high standard And the ability to work under pressure and to tight deadlines in a dynamic environment
16. Ability to work effectively as part of a team, as well as independently with minimal supervision
17. Ability to adapt and learn new areas of law.

## VERIFICATION

This section verifies that the line manager and appropriate senior manager/executive confirm that this is a true and accurate reflection of the position.

| Line Manager |  | Delegated Authority |                            |
|--------------|--|---------------------|----------------------------|
| Name:        | Jade Greenhalgh                        | Name:               | Jakob Vujcic               |
| Title:       | Senior Manager Regulatory & Compliance | Title:              | GM Regulatory & Governance |
| Signature:   |  | Signature:          |                            |
| Date:        |  | Date:               |                            |