CANDIDATE INFORMATION BOOKLET

Open competition for appointment to the position of:

**Certification and Inspection Officer – Medical Devices Division - SSO Grade**

**National Standards Authority of Ireland**

**Closing Date:**

**09/11/2020, 5pm**

PLEASE READ CAREFULLY

GDPR Privacy Statement is appended to the back of the booklet

National Standards Authority of Ireland is committed to a policy of equal opportunity

**Contact: NSAI Human Resources Department on 01 8073839 or at**

**1 Swift Square, Northwood, Santry, Dublin 9, Ireland**

**Telephone Number: (353) 1 8073839**

**URL: https://www.nsai.ie/**

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| Job Description |
| Job title: | Certification and Inspection Officer |
| Division: | Medical Devices |
| Department: | Medical Devices  |
| Reports to: | European Operations Manager |
| Grade: | SSO |
| Ref:  | 12-20 |
| FTE: | Full time |
| Status:  | Permanent |
| location | Ballybrit, Galway. |

**Job Overview**

NSAI is seeking to recruit a certification and inspections officer for medical devices with experience in one or more of the following areas:

* Active devices
* Software in medical devices
* Vascular devices
* Cardiology devices
* Respiratory devices
* Orthopaedic devices
* Ophthalmology
* Wound care devices
* Neurology devices
* General medical devices
* Devices incorporating tissue of animal origin
* Drug device combinations
* Sterilisation and Biocompatibility

The role will include performing regulatory Quality Management System (QMS) audits under the medical devices regulation, as well as reviewing technical file dossiers submitted by manufacturers for CE mark approval of medical devices. Due to the nature of quality management system audits, this post will require the individual to be off site at least half of the time.

**Key Tasks and Responsibilities**

* Conduct registration, surveillance and recertification activities at client facilities to assess their conformity to the related management system standard.
* Conduct the above audits and prepare the associated pre and post audit documentation in accordance with all NSAI procedures.
* Perform technical reviews of product Technical documentation to determine compliance with applicable standards and regulations, and to ensure safety and performance.
* Communicate with assigned clients and NSAI staff to ensure efficient audit planning and timely resolution of questions and non-conformities.
* Stay abreast of technology and regulatory trends affecting certification.
* Promote the Certification/Inspection service through the dissemination of information by correspondence, lectures and publications or otherwise as the opportunity arises.
* Respond to technical enquiries and have responsibility for timely communication and support to clients, administrative staff and Medical Device team members.
* Maintain strict confidentiality of matters relating to client work at all times.
* Undertake travel to evaluate applications for certification and registration schemes operated by NSAI.
* Perform any other duties as may be required by the European Operations Manager.

**Qualifications and Experience Essential:**

* Successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, biotechnology, biomedical science, engineering or other relevant sciences.
* Four years professional experience in the field of healthcare products or related activities, such as manufacturing, auditing or research of which two years shall be in the design, manufacture, testing or use of the medical device or technology in one or more of the following areas:
	+ Active devices
	+ Software in medical devices
	+ Vascular
	+ Tissue of animal origin
	+ Drug device combinations
	+ Cardiology
	+ Respiratory
	+ Orthopaedics
	+ Ophthalmology
	+ Wound care
	+ Neurology
	+ General Medical devices
* Two years-experience in the area of quality management.

**Technical Competencies Essential**

* Knowledge of the Medical Device Regulation 2017/745.
* Knowledge of quality management systems (ISO 13485) and related standards and guidance documents.
* Knowledge of device legislation, harmonised standards, guidance documents.
* Knowledge of risk management and related device standards and guidance documents.
* Experience, training or qualification as QMS (quality management systems) Auditor or QMS Lead Auditor under ISO 13485, with preference given to Notified Body experience.
* Strong understanding of international regulatory requirements for medical devices, with particular emphasis on European requirements.
* Understanding and working knowledge of International Standards for medical devices, such as ISO, EN, IEC, ASTM, ANSI and/or AAMI.
* Ability to analyse data and write clear, concise summary reports.

**Core Competencies:**

* Good interpersonal skills, with the ability to relate to people at all levels within and outside the NSAI.
* Ability to work on own initiative and to work as a team member.
* Strong presentation skills and high level of computer literacy required.

**Key Competencies for Certification and Inspection Officer**

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| **Leadership**  |
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| * Actively contributes to the development of the strategies and policies of the Department/ Organisation
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| * Brings a focus and drive to building and sustaining high levels of performance, addressing any performance issues as they arise
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| * Leads and maximises the contribution of the team as a whole
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| * Considers the effectiveness of outcomes in terms wider than own immediate area
 |
| * Clearly defines objectives/ goals & delegates effectively, encouraging ownership and responsibility for tasks
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| * Develops capability of others through feedback, coaching & creating opportunities for skills development
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| * Identifies and takes opportunities to exploit new and innovative service delivery channels
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| **Judgement, Analysis & Decision Making**  |
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| * Researches issues thoroughly, consulting appropriately to gather all information needed on an issue
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| * Understands complex issues quickly, accurately absorbing and evaluating data (including numerical data)
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| * Integrates diverse strands of information, identifying inter-relationships and linkages
 |
| * Uses judgement to make clear, timely and well grounded decisions on important issues
 |
| * Considers the wider implications, agendas and sensitivities within decisions and the impact on a range of stakeholders
 |
| * Takes a firm position on issues s/he considers important
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| **Management & Delivery of Results** |
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| * Takes responsibility for challenging tasks and delivers on time and to a high standard
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| * Plans and prioritises work in terms of importance, timescales and other resource constraints, re-prioritising in light of changing circumstances
 |
| * Ensures quality and efficient customer service is central to the work of the division
 |
| * Looks critically at issues to see how things can be done better
 |
| * Is open to new ideas initiatives and creative solutions to problems
 |
| * Ensures controls and performance measures are in place to deliver efficient and high value services
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| * Effectively manages multiple projects
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| **Interpersonal & Communication Skills** |
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| * Presents information in a confident, logical and convincing manner, verbally and in writing
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| * Encourages open and constructive discussions around work issues
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| * Promotes teamwork within the section, but also works effectively on projects across Departments/ Sectors
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| * Maintains poise and control when working to influence others
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| * Instills a strong focus on Customer Service in his/her area
 |
| * Develops and maintains a network of contacts to facilitate problem solving or information sharing
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| * Engages effectively with a range of stakeholders, including members of the public, Public Service Colleagues and the political system
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| **Specialist Technical Knowledge, Expertise and Self Development** |
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| * Has a clear understanding of the roles objectives and targets of self and the team and how they fit into the work of the unit and Department/ Organisation
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| * Has a breadth and depth of knowledge of Department and Governmental issues and is sensitive to wider political and organisational priorities
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| * Is considered an expert by stakeholders in own field/ area
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| * Is focused on self development, seeking feedback and opportunities for growth to help carry out the specific requirements of the role
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**Application and Selection Process**

**How to Apply**

Please submit the 3 documents as set out below to human.resources@nsai.ie by close of business on **5pm, 09/11/2020.**

1. A comprehensive CV detailed as relevant to the position (no longer than 3 pages);
2. A short cover letter/ personal statement (i.e. no more than 2 pages)outlining why you wish to be considered for the post and where you believe your skills and experience meet the requirements for the position.
3. Completed NANDO form.

We request that **all three documents are submitted in a single word document or PDF** where possible.

**Please note** that omission of any or part of the 3 requested documents, as set out above, will render the application incomplete. Incomplete applications will not be considered for the next stage of the selection process.

**Requests for Reasonable Accommodations**

NSAI, in line with the Employment Equality Acts 1998-2015, will ensure that it does all that is reasonable to accommodate the needs of a person who has a disability and will ensure that its services are accessible across the range of disabilities.

If you require reasonable accommodations made, please indicate this during the application process by emailing human.resources@nsai.ie by writing to the following address: HR Department, NSAI, 1 Swift Square, Northwood, Santry, Dublin 9 DO9 AOE4. Any requests for reasonable accommodation need to be accompanied by a medical/psychologist’s report, the purpose of which is to provide NSAI with information necessary to make the decision on reasonable accommodation as promptly as possible. NSAI will consider each request on a case by case basis. All information provided will be treated as strictly confidential.

**Requests for Documentation/Information in an Alternative Format**

All documents/information related to the application process is available in an alternative format. You can make a request for documents/information in an alternative format by emailing human.resources@nsai.ie or in writing to the following address: HR Department, NSAI, 4th Floor, 1 Swift Square, Northwood, Santry, Dublin 9 DO9 AOE4.

Please provide the following details when making a request:

* Name, address, contact details
* Details of document/information being requested
* The information format sought

All requests will be acknowledged within 3 working days of receipt and will be dealt with within 10 working days. Where a delay in providing the requested information occurs, NSAI will confirm the new date the person can expect to receive the information. If NSAI is unable to provide the requested information, the reason will be explained fully in writing to the person making the request.

**Closing Date**

**The closing date and time for applications is 09/11/2020. Applications received after the specified deadline will not be accepted.**

*If you do not receive an acknowledgement of receipt of your application within 2 working days of applying, please email* *human.resources@nsai.ie*

**Selection Methods**

NSAI will convene an expert board to carry out the competitive stages of the selection process to the highest standards of best practice. The approach employed may include:

* Shortlisting of candidates on the basis of the information contained in their application;
* A competitive, competency focussed, interview;
* A second-round interview (if applicable);
* Presentation/Work sample/role play/media exercise, and any other tests or exercises that may be deemed appropriate; and
* Reference and online checks.

**Shortlisting**

Based on the number of applications received, the NSAI may in the first instance conduct a shortlisting exercise.

During any short-listing exercise that may be employed, NSAI is guided by an interview board who examine the applications and assess them against pre-determined criteria based on the requirements of the position. It is therefore in your own interest to provide a detailed and accurate account of your qualifications/experience on your application.

Prior to recommending any candidate for appointment to this position NSAI will make all such enquiries that are deemed necessary to determine the suitability of that candidate. Until all stages of the recruitment process have been fully completed a final determination cannot be made nor can it be deemed or inferred that such a determination has been made.

**Interviews**

The onus is on each applicant to ensure that she/he is in receipt of all communications from NSAI. Candidates should make themselves available on the date(s) specified by NSAI and should make sure that their contact details specified on their application are correct. NSAI will not be responsible for refunding any expenses incurred by candidates for attendance at interview.

**NSAI Recruitment and Selection Review Process**

In relation to all NSAI recruitment campaigns, Human Resources (HR) take all necessary steps to ensure a fair, open and transparent appointment process that produces a quality outcome and commands public confidence.  HR also abides by the core recruitment principles of probity, equity and fairness, selection based on merit, and best practice, which are observed in all NSAI recruitment processes.  All appointments made will also comply with relevant employment and equality legislation, and all candidates will be treated fairly, to a consistent standard and in a consistent manner.

Stage One Review: When a request for a review of a selection decision is received from a candidate every effort is made to resolve the matter at Stage One by e.g. providing feedback to the candidate.  The Stage One Review process may be availed of within five working days of notification of the initial decision, and should normally take place between the candidate and the person who communicated the decision.

HR will carry out the Stage One Review without delay and within a period of time that enables the candidate to avail of the Stage Two Review procedures within the specified timelines should he/she so wish.  Where a candidate remains dissatisfied following a Stage One Review, he/she may adopt the Stage Two procedures set out below. If the candidate wishes the matter to be dealt with by way of a Stage Two Review, he/she must notify HR within two working days of the notification of the outcome of the Stage One review. Recruitment and selection processes will not be suspended pending the outcome of a review.

Stage Two Review: The candidate must address his/her concerns in relation to the process in writing to the Head of HR, setting out those aspects of the action or decision in relation to his/her candidature that he/she wishes to have reviewed.

The candidate must support their request for review by outlining the facts they believe show the action/decision taken was wrong.  A request for review may be refused if the candidate cannot support their request.

The case will be reviewed by a person other than any individual directly associated with the decision in question.  The person(s) conducting the Stage Two Review will consider any written submissions made by the candidate, and all other relevant information, including any relevant e-mails, notes or memoranda held by HR in respect of the selection process. Where necessary, the reviewer may meet with the personnel involved in the selection process and/or the candidate for the purpose of eliciting further information. The outcome will generally be notified to the candidate within 10 working days of receipt of the complaint or request for review. Where the investigation does not allow a decision within this timeframe, the reviewer will keep the candidate informed of the status of the review. The decision of the Stage Two reviewer is final.

**Candidates’ Rights–** **Review Procedures in relation to the Selection Process**

NSAI will consider requests for review in accordance with its Recruitment & Selection Policy.

**References**

NSAI would appreciate it if you would start considering names of people who you feel would be suitable referees (1 - 2 names and contact details). The referees listed do not have to include your current employer but should be in a position to provide a work reference for you. Please be assured that NSAI will only collect the details and contact your referees should you come under consideration at interview stage.

The admission of a person to a competition, or invitation to attend interview, or a successful result letter, is not to be taken as implying that NSAI is satisfied that such a person fulfils the requirements or is not disqualified by law from holding the position.

Should the person recommended for appointment decline, or having accepted it, relinquish it, NSAI may at its discretion, select and recommend another person for appointment from the panel on the results of this selection process.

**Deeming of candidature to be withdrawn**

Candidates who do not attend for interview or other selection processes when and where required by NSAI, or who do not, when requested, furnish such evidence as NSAI require in regard to any matter relevant to their candidature, will have no further claim to consideration.

**Principal Conditions of Service**

**Remuneration:**

Level SSO Contributory Salary scale: €62,508 (Point 1), €65,426 (Point 2), €68,344 (Point 3), €70,180 (Point 4), €73,018 (Point 5), €75,857 (Point 6), €78,695 (Point 7), €81,520 (point 8), €84,369 (point 9), €86,948 (LSI 1\*) €89,923 (LSI 2\*) p.a.

Level SSO Non-Contributory Salary scale: €59,473, (Point 1), €62,249 (Point 2), €65,018 (Point 3), €67,791 (Point 4), €69,498 (Point 5), €72,197 (Point 6), €74,891 (Point 7), €77,576 (point 8), €80,283 (point 9), €82,733 (LSI 1\*) €835,561 (LSI 2\*) p.a. (only applicable for relevant category of Civil/Public Servants)

\*Please note this increment is applicable after 3 years’ service on the previous point

All appointments are made in accordance with the Department of Finance and the Department of Public Expenditure and Reform guidelines.

Salary implications for existing Civil/Public servants should be queried with HR Unit, NSAI.

**Starting Salary**

Candidates should note that entry will be at the first point of the appropriate scale and will not be subject to negotiation. The rate of remuneration may be adjusted from time to time in line with Government pay policy.

**Duties of the Post**

The duties and responsibilities set out in this job description are indicative of responsibilities related to this role. As with all posts, the nature of NSAI business is evolving and flexibility is required to adapt to changing business needs.

**Annual Leave**

Annual Leave 30 working days and this leave is exclusive of Public Holidays.

**Hours of Attendance**

Working hours are from 9:00 to 17:15 on Monday to Thursday and 9:00 to 16:45 on Friday, with 45 minutes lunch break unless otherwise stated. No additional payment will be made for extra attendance as the rate of remuneration payable covers any exceptional extra attendance liability that may arise from time to time.

**Tenure**

The appointment will be on a full-time permanent basis. The appointee must serve a probationary period, which lasts for 12 months. Should the appointee’s service be satisfactory with regards to health, conduct, and efficiency generally during the probationary period, the appointee, on completion of the period will be finally appointed. Should the appointee’s services be unsatisfactory, the appointment may be terminated at any time during the period.

**Location**

This position will be based at 1 Swift Square, Northwood, Santry, Dublin 9.

**Confidentiality and Conflict of Interest**

Employees are prohibited from having any personal or financial interest in any industry that NSAI certifies from the date of appointment with the NSAI. Employees are prohibited from disclosing any information in relation to the business of any person obtained in his/her capacity as an officer of the NSAI.

**Superannuation and Retirement**

The appointee will be offered public service pension terms and retirement age conditions in accordance with pension arrangements in NSAI depending on the status of the successful appointee:

a) In general, an individual who has no prior pensionable Public Service history in the 26 weeks prior to appointment will be a member of the Single Public Service Pension Scheme (Single Scheme) which commenced from 1 January 2013 [Section 10 of the Public Service Pensions (Single Scheme and Other Provisions) Act 2012 refers];

b) An individual who was a member of a “pre-existing public service pension scheme” as construed by the Public Service Pensions (Single Scheme and Other Provisions) Act 2012 and who does not qualify for membership of the Single Scheme will have standard public service pension terms reflecting new entrant or non-new entrant status for the purposes of the Public Service Superannuation (Miscellaneous Provisions) Act 2004.

**Appointee’s status for superannuation purposes**

Appointees will be required to disclose their full public service history. Details of the appropriate superannuation provisions will be provided upon determination of appointee’s status. The following points should be noted:

**Pension Accrual**

A 40-year limit on total service that can be counted towards pension where a person has been a member of more than one existing public service pension scheme will apply. This 40-year limit, which is provided for in the Public Service Pensions (Single Scheme and other Provisions) Act 2012 came into effect on 28 July 2012. This may have implications for any appointee who has acquired pension rights in a previous public service employment.

**Pension Abatement**

The Public Service Pensions (Single Scheme and Other Provisions) Act 2012 extended pension abatement so that a retiree’s public service pension is liable to abatement on re-entering public service employment, even where the new employment is in a different area of the public service. However, if the appointee was previously employed in the Civil Service and awarded a pension under voluntary early retirement arrangements (other than the Incentivised Scheme of Early Retirement (ISER) or the Health Service Executive VER/VRS which render a person ineligible for the competition) the entitlement to payment of that pension will cease with effect from the date of reappointment.

**Ill-Health Retirement**

Please note that where an individual has retired from a Civil/Public Service body on the grounds of ill-health his/her pension from that employment may be subject to review in accordance with the rules of ill-health retirement within the pension scheme of that employment.

**Annual Superannuation Contribution (ASC)**

This appointment is subject to the ASC deduction as provided for under Part 4 of the Public Service Pay and Pensions Act 2017.

For further information in relation to public service superannuation issues please see the following website: <http://per.gov.ie/pensions>

**GDPR Privacy Statement- Recruitment Process**

**Purpose of Processing**

NSAI conducts a competency-based recruitment process to fill vacancies within the organisation. To complete this, interested individuals are asked to submit a CV and Cover Letter. For the successful candidate, some of the information provided will form the basis of the contract of employment (e.g. address).

**Legal Basis for Processing**

* Necessary for performance of a contract or to enter into such a contract
* Compliance with legal obligation (Terms of Employment Information Act)

**Recipients**

The following shall receive your information for reasons outlined below:

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| --- | --- |
| **Recipient**  | **Reason** |
| HR (internal)  | Storing application, acknowledging responses and corresponding with applicants.  |
| HR (external Service provider)  | If outsourced support is sought, NSAI’s outsourced HR provider may receive applications to assist with elements of administration, or to manage the entire recruitment process. |
| Interview Panel | The Interview Panel will receive your applications to conduct shortlisting and assessing applicants.  |
| Referees | Applicants are asked to provide references for people who can be contacted to validate work records and/or comment on suitability of the applicant for the NSAI position in question. These people shall be contacted, and the applicants name will need to be provided to receive the reference.  |
| Company Doctor | NSAI will use your personal details to refer you to the company doctor if considered for appointment. |

**Details of Data Transfers Outside the EU**

This does not apply to this process.

**Automated Decision Making**

This does not apply to this process.

**Retention Period for Data**

For unsuccessful candidates, applications and correspondence shall be retained for 2 years. For successful candidates, their application will be placed on their employee file and retained during their employment and for 7 years thereafter.

**Your GDPR Rights in Relation to this Process**

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| **Right**  | **Explanation** |
| Access | You can request and receive access to the information requested in the process at any time. |
| Portability | You can request and receive a copy of this data, in electronic/transferable format, at any time.  |
| Erasure | You can request the data held be erased. We have outlined the anticipated retention period above.  |
| Rectification  | You can request that any incorrect information, due to this information being updated or otherwise, be corrected.  |
| Objection | You can object to this information being processed  |

If you have any questions or complaints about NSAI’s use of your personal data, please contact NSAI’s Data Protection Officer:

* By post: Data Protection Officer, National Standards Authority Ireland, 1 Swift Square, Northwood, Santry, Dublin 9 DO9 AOE4 by phone: +353 1 8073800

You also have the right to lodge a complaint with the Data Protection Commission if you are not happy with the way we have used your information or addressed your rights. Details of how to lodge a complaint can be found on the Data Protection Commission’s website.