Application to amend device registration number NR-1385-D-101-E and US NRC Exempt Distribution License 04-35093-01E to add a location of manufacturer and a location of distribution

SCION INSTRUMENTS

November 10, 2015

Duplicate Copy

Prepared by:

IRSC
International Radiation Safety Consulting, Inc.
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Application to amend device registration number
NR-1385-D-101-E and US NRC Exempt Distribution License 04-35093-01E
Techcomp DBA Scion Instruments

Index of attachments

Techcomp DBA Scion

US NRC Device Registration and Distribution License Amendment

11/11/2015

Attachment A-QA Plan for Netherlands Site
Attachment B- QA Plan for TX Site
Attachment C-License for Netherlands Site
Attachment D- Organizational Chart

Techcomp
America

November 11, 2015

Tomas Herrera
Team Leader
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

RE: License Amendment for US NRC Exempt Distribution License 04-35093-01E and Exempt Device Registration NR-1385-D-101-E to add Location of Distribution and add Location of Manufacture

Dear Mr. Herrera:

Techcomp USA, DBA Scion Instruments, requests an amendment of distribution license 04-35093-01E, and device certificate NR-1385-D-101-E, in order to add a location of distribution, and add an additional location of manufacture. This information is as follows:

1. The new US distribution location is 3019 Alvin Devane Suite 120, Austin, TX, 78741.

2. The location of manufacture is Techcomp Europe Ltd DBA Scion Instruments located, at Stanleyweg 4, 4462 GN GOES, NETHERLANDS.

Enclosed is the supporting documentation for our request.

We have a pending new license application with the state of Texas for possession of Electron Capture Detectors incident to exempt distribution.

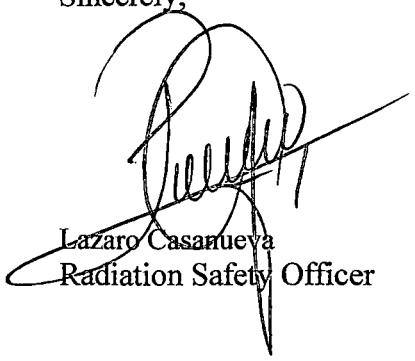
It is our intention to phase out manufacturing and distribution from the California site, and we request dual distribution from both Austin Texas and Freemont California until this transition is complete.

Our consultant is International Radiation Safety Consulting, Inc. (IRSC). Its personnel are authorized to discuss our applications, licenses, and device registrations with you on our behalf.

I will be replacing Trung Tu as the Radiation Safety Officer. If you have any questions please call me at 305.610.2656 or email me at lazaro.casanueva@techcomp-am.com.

Techcomp
America

Sincerely,



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Radiation Safety Officer

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SCION INSTRUMENTS	Process Work Instruction Radiation Safety Manual REPORTING (NEAR) ACCIDENTS AND INCIDENTS	ARB-02	Rev. TBD
		Date 11/3/15	
		Page 1 of 2	

Originator	Approved:	Date:
Associated Part No N.A. 101 & 201	Approved:	Date:

1.0 GENERAL

In the event of an emergency, it is necessary to act first and report it later.
Accidents, near accidents and other types of incident (including suspect persons, packages and situations) shall be reported so that preventative measures can be put in place in order to prevent their recurrence.
Reporting a situation, other than a (near) accident or an incident, can be done using Reporting Undesired Situations (KWA-02).

2.0 EXECUTION

2.1. Immediate:
In the event of an **accident** it is necessary to involve, immediately after performing first aid measures (where necessary), your superior and also the KAM manager or his/her substitute so that all possible information can be collected on the situation.
In the event of an **incident** (such as burglary, theft, vandalism, suspect persons/packages/situations, etc), this must be immediately reported to the superior or (another) manager, Reception, Facilities or the KAM manager. Action must then be taken to prevent the situation worsening. It may be necessary to call the police. Access to or interference with the site of a burglary or theft must be kept to a minimum.
(In the event of a **facility emergency** (fluid/gas leak, window broken by wind, etc) see IKZ-FAC-02.)

2.2. Reporting:
A written report of the (near) accident/incident must be drawn up within one day of the event so that as many details as possible can be accurately reported, unless the manager concerned should require it sooner.
All those best able to describe the situation of the (near) accident or incident shall provide a report using an **accident/incident report**, in which the situation shall be described by responding to a set of questions.

Send the completed report (a printout or digital version) to the following persons:

immediate superior; in order to determine the measures that need to be implemented so that such a situation does not recur.

KAM manager; who shall assess whether the incident needs to be reported to the Health and Safety Inspectorate (in the event of a serious accident) and/or to the OSHA (Occupational Safety and Health Administration) or to the International Trade Compliance manager.

2.3. Checks:

The KAM Manager registers the incoming reports and handles contact with the Health and Safety Inspectorate, OSHA (through Scion) and the International Trade Compliance Manager.
The Facilities Manager handles any follow-up issues (where necessary) with the Police.
Depending on the type of problem, the manager concerned checks the status of any improvement actions. This either means the verification of the measures taken or ordering action to be taken. This order is of a binding nature.

Change Record

Revision	Change Description	Date	Initiated By:

scion INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **RADIOACTIVE SOURCES (ECD)**	ARB-03	Rev. Initial
		Date 11/3/15	
		Page 1 of 5	
Originator: P.	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

This procedure outlines how to proceed in the case of detectors that contain a radioactive source.

2.0 SCOPE

This procedures applies to Scion Instruments authorized users who perform semi-annual leak testing, ship ECDs to customers, and receive ECDs from a customer.

3.0 DEFINITIONS AND ABBREVIATIONS

3.1. Scion holds a permit from the Ministry of Housing, Spatial Planning and the Environment to use and keep in stock the 'closed sources' (also known as 'sealed sources') outlined in detail below.

This permit states, inter alia, that Scion:

3.1.1. shall have at least one level 5A **specialist** in Ionizing Radiation; at Scion this person is dit Kees Nijsse,

3.1.2. a periodic **inspection for radioactive contamination** (the so-called wipe test) must be performed;

3.1.3. Scion has this performed for it by Röntgen Technische Dienst (RTD) or an equivalent body,

3.1.4. a **comprehensive record** must be kept of all sources present (incoming, in use and outgoing) by Customer Services,

3.1.5. **storage** must be achieved in a recognizable, specially created, suitable and fire-resistant location, if separate ECD cells and ECDs are not employed;

3.1.6. Scion has two (2) safes for this purpose at Production Instruments (I020). The storage areas have been made clearly recognizable from the exterior by means of pictograms.

3.2. ECDs are detectors in which a sealed radioactive source (the ECD cell, also referred to sometimes as the 'source container') is fitted. ECDs are detectors in which a sealed radioactive source (the ECD cell, also referred to sometimes as the 'source container') is fitted. A nickel foil is placed in this ECD cell (the so-called 'open source') which contains the ß--nuclide Ni-63 with activity of a maximum of 555 MBq (15 mCi).

3.3. Third parties attach and remove this radioactive foil in an ECD cell, as well as check for radioactive contamination of the ECD cell and the ECD detector casing.

3.4. Working with an ECD – in other words, conducting analyses using an ECD in a GC, assembling or disassembling an entire detector unit in a GC and assembling or disassembling the detector unit itself (specifically **only** opening the ECD cell) – shall only be performed by properly trained employees working under the control of a specialist in these areas with a least a level 5A Ionizing Radiation diploma.

4.0 SAFETY

4.1. Scion has set up a so-called , which is signed (as having been read, understood and agreed to) by all employees working with an ECD and is submitted to the radiation protection officer for inclusion in the radiation file. This ECD instruction must be strictly complied with.

4.2. The same ECD work instruction applies at every permanent GC equipped with an ECD.
As a rule, it is necessary to avoid picking up ECDs with one's bare hands as far as possible. Even though care is taken to ensure that work is only undertaken using externally uncontaminated, sealed sources, maximum care is still required at all times.

4.3. Good personal hygiene is of great importance in this regard. Always wash your hands after completing your work.
In addition, care must be taken to ensure that the ECDs do not become hotter than the permitted temperature.

4.4. A GC with an ECD fitted must, in the event of an emergency in Production, be identifiable at a distance to emergency services. It has been agreed for this purpose that a moveable sign bearing the radioactivity symbol shall be hung above (or at least immediately next to) every system containing a detector with a radioactive source.
Staff are obliged to store all separate ECD cells and ECDs in one of the (locked) storage areas, as listed in the introduction, after work. During working hours, they can obviously be kept outside of the storage areas, if it is permitted to use them on that day.
If in doubt or in the event of an emergency, the radiation protection officer responsible for radioactive materials (see introduction) shall be informed.

Micheal Ots (now a certified radiation protection officer) may only be consulted in the absence of the radiation protection officer.

Instructions issued by the person indicated above must be followed immediately.

5.0 COMPULSORY REGISTRATION

5.1. Each ECD has a unique serial number displayed on the outside of the detector to allow the identification of this radioactive source. It is extremely important that all information on the radioactive sources is correct in the database as regards whether they are present and their proper location. N.B. All changes concerning the location and owner shall be indicated to the person responsible in Customer Services, max.westdorp hereafter to be referred to as **Max**.

5.2. The aim is to ensure that things run smoothly and that the rules are complied with.

6.0 WIPE TEST CERTIFICATES

When delivered to the customer, the date on the wipe test certificate may be no more than six (6) months prior. Given the lead time in Production, it is important that the wipe test certificates for the storage areas for radioactive sources (hereafter referred to as the ECD storage areas) are no more than five (5) months' old. Customer Services (Max) monitors these expiry dates and ensures that a new wipe test is completed, either during the annual wipe test session or at another time.

7.0 LOGISTICAL ROUTING

7.1. **For ECDs (Bruker/Scion)**

7.1.1. Receipt of the ECD cells for assembly into an ECD:

7.1.1.1. ECD cells are ordered by MM from Eckert & Ziegler (formerly QSA Global/Nuclitec) in Germany.

7.1.1.2. When they arrive, the serial numbers of the ECD cells on the packing list are given to Max by Goods Receipt (GR) for the central sources' records.

7.1.1.3. On the same day, GR places the ECD cells (including the accompanying source certificates) in the safe in Production Instruments, Assembly department (I020 location IA).

7.1.2. Assembly of the ECDs:

7.1.2.1. Production Instruments, Assembly department removes the required ECD cells from the safe (I020; **First in – First Out**), assembles the ECD and stores it in the box with the documents in the safe in Production Instruments (I020, location IG).

7.1.2.2. On the same day, the Assembly department provides Max with the serial numbers and model numbers (format 02-001972-xx) for registration purposes.

7.1.3. Incorporating the ECDs and testing them:

7.1.3.1. In case of an order for a GC+ECD, Production Instruments removes an ECD from the safe (I020; **First in – First Out**, location IG) to be able to incorporate and test it.

7.1.3.2. In the case of the Final Test, it is checked whether the wipe test certificate is no more than six months' old, otherwise Max needs to be informed and he will then take further action.

7.1.4. Delivery of a GC+ECD or separate ECD to the Warehouse:

7.1.4.1. Once the Final Test has been passed, the ECD is removed and placed on the 'trolley'. If it is a GC+ECD, the radioactivity sticker is not stuck on to the accompanying GC but is rather delivered unattached.

7.1.4.2. Production Instruments then immediately notifies Max (by e-mail) of the ECD serial number and (where applicable) of the accompanying GC number.

7.1.4.3. Production Instruments also states whether or not this ECD will be delivered with the GC. If not, then the ECD is sent to **the safe in Production Instruments, Assembly department (I020, location IG).**

7.1.4.4. As regards the next phase: see '*Shipping an ECD*'

7.2. Shipping an ECD

7.2.1. Once the Warehouse has collected the articles from the trolley, there is a choice of two (2) options in the Warehouse, depending on the situation known at the time of the receipt of the order or which is announced later by CS:

7.2.1.1. If CS is satisfied that shipping and delivery to the customer will not result in any problems, the ECD and the wipe test, source certificate + required materials (see BOM) are packed and readied for shipping in accordance with the instructions from CS. CS ensures shipment takes place in the proper manner. CS ensures shipment takes place in the proper manner.

7.2.1.2. If an ECD customer is not yet permitted to receive the ECD or if the shipment needs to be completed in a special manner, the ECD and required materials are, on the same day, placed by the warehouse in the designated location in the ECD storage area LO1, **the safe in Production Instruments, Assembly department (I020)**. The GC (without the radioactive sticker) is packed (without the ECD) and shipped in the standard manner. The ECD waits to be shipped as outlined below under **'separate ECD's.**

7.3. Separate ECDs:

The packing list for shipping an ECD shall be provided by the Warehouse or CS to Max (depending on where the packing list is printed out). Max processes it in the records and enters the serial number of the ECD (along with the wipe test certificate that is no more than 6 months' old) to be delivered on to the packing list. The Warehouse removes this article from **storage area I020, location IG (ECD)** and it is then shipped through dispatch.

7.4. **Returned ECDs:**

7.4.1. NB. N.B. No repairs are undertaken on ECDs within Scion

7.4.2. ECDs may be returned for refurbishing or rebuild (exchanged for a new one) or on the basis of a complaint (in consultation with Technical Support using an RMA) or for (assessment for) disposal. Upon arrival at GO, this shall always be immediately reported to Max (for ECD).

7.4.2.1. ECDs returned due to a complaint: GO informs Max (for ECD) in order to ensure it is registered and dealt with according to the RMA. ECDs can be, if necessary, further checked by the vendor of the ECD cell.
NB. Work is only performed on complaints if it has a no more than three months' old wipe test certificate. If this is not the case, then the ECD is sent by Max (for ECD) to RTD for a new wipe test. The costs incurred are charged to the sub/dealer.

7.4.2.2. ECDs sent in for (assessment for) disposal and ECDS sent in for rebuilding: GO informs Max (for ECD) to ensure they are registered. If it is decided (generally by TS) that the ECD needs to be removed, then the entire ECD is, under Max's supervision (for ECD), placed in a container for radioactive waste in safe I020, location IG (ECDs). Actual removal to COVRA (the Central Organization for Radioactive Waste) is organized periodically by Max (for ECD).

Change Record

Revision	Change Description	Date	Initiated By:

1.0 INTRODUCTION:

1.1. Approved suppliers

1.1.1. Goods required for daily operations may only be purchased from suppliers that are designated as having been approved (not flagged for deletion) in sap (information system).

1.1.2. In order for a company to appear as an approved supplier in sap, a number of requirements must be fulfilled. This is checked by means of an initial inspection.

1.1.3. As not all suppliers are equally strategically important, the strictness of the inspection differs.

1.1.4. Nb. Suppliers that were already in sap prior to 2003 are excluded from the need for initial inspection.

1.1.4.1. So-called 'one-off vendors' do not have to be assessed in line with this procedure.

1.1.4.2. Suppliers that have been introduced by other Scion plants are also excluded from the need for this inspection.

1.1.4.3. C suppliers do not require an initial inspection.

1.2. Type of supplier:

1.2.1. A supplier: a supplier of strategically important goods.

1.2.1.1. Definition:

1.2.1.1.1. The availability of goods is complex.

1.2.1.1.2. High importance and risk.

1.2.2. B supplier: a supplier of critical goods

1.2.2.1. Definition:

1.2.2.1.1. The availability of goods is reasonable, but, before the supplier is able to deliver the product, supervision and checks are required by Scion

1.2.2.1.2. Average importance and risk.

1.2.3. C supplier: a less important supplier (non-critical and non-strategic)

1.2.3.1. Definition:

1.2.3.1.1. Availability of products is straightforward, mostly standard articles.

1.2.3.1.2. Low importance and risk.

1.3. Matrix

Scion suppliers

1.4. Criteria for inclusion on the "APPROVED SUPPLIERS" list

	Transfer time < 1 month	**1 - 6 months**	**> 6 months**
Purchase volume < €10,000	**C**	**B**	**B**
Purchase volume < €10,000 – 100,000	**C**	**B**	**A**
Purchase volume < €100,000	**B**	**A**	**A**

1.5. A questionnaire must be completed for each supplier (apart from the exceptions indicated above). This questionnaire is also available in a form where the supplier section is in *English.*

1.6. The number of questions to be answered depends on the type of supplier (a or b). This is indicated for each question (e.g. Ab: to be completed for a and b suppliers only).

1.7. Once the form has been completed, and following assessment and authorization, the supplier is added to sap as an approved supplier.

1.8. In most cases, new (a + b) suppliers will first have to make a trial delivery before they can be admitted to the list. The assessment is in part dependent upon the quality of this trial delivery.

Change Record

Revision	Change Description	Date	Initiated By:

1.0 PURPOSE

This procedure outlines the way in which internal quality audits are planned and implemented.

2.0 SCOPE

The purpose of the internal quality audit is to assess whether the quality system is still functioning efficiently. This entails the following:

- checking whether all ISO requirements are met
- checking whether all quality documents are up to date
- checking whether work/actions are in accordance with the procedures and instructions
- checking whether the communication/transfers between departments result in problems
- checking whether the quality system is efficient, easy to use and ergonomic
- checking whether efforts are continuously being made to keep the quality system up to standard

checking whether ideas/initiatives exist for improving the quality of the organization, its processes and products.

3.0 DEFINITIONS AND ABBREVIATIONS

- Internal quality audit:
  A systematic and independent investigation to determine whether quality activities and the results linked to them correspond to the quality policy and the quality objectives.
- Non-conformity (NC):
  An identified fault within the quality system when compared with ISO-9001 requirements, which must be corrected.
- Recommendation/attention point:
  An identified fault in the quality system or an option for improvement, without a corrective measure being obligatory.
- Auditor:
  A qualified assessor appointed by the QA manager. An auditor must have both expertise in materials and experience in conducting audits. The latter means that an auditor must have either taken part in an external workshop on internal audits or must have participated in the preparation and implementation of at least two internal audits under the supervision of a qualified auditor.

4.0 PROCEDURE

4.1. **Area of application:**

4.1.1. Internal quality audits pertain to all components of the quality system, as detailed in the quality care system.

4.2. **Implementation:**

4.2.1. Planning: The QA manager is responsible for the preparation and organization of internal audits. He drafts an audit plan each year and determines the frequency with which internal audits are to be held. The basic arrangement is that every component must be assessed at least once every three years. A higher frequency may be applied should the situation require it. The period during which the audit will be performed in a given department is stated in the audit plan.

4.2.2. Preparation by the QA manager: The QA Manager informs the team that is to conduct the internal audit about the audit to be performed and the period concerned. This team consists of at least one qualified auditor who is not part of the department where the audit is to be held. In general, two auditors are used, one of whom acts as the lead auditor.

4.2.3. Preparation by the auditors:

4.2.3.1. A date for the audit is set in consultation with the team leader/manager of the department – the last week of the tax month must be avoided, and the persons working in the department that are relevant to the audit must be present.

4.2.3.2. The auditors and the QA manager discuss which components of the audit must receive the most attention no less than two weeks prior to the audit. If necessary, the auditors will receive the relevant ISO-9001 sections and background information.

4.2.3.3. The department regulations are requested for perusal and studied together with the relevant IKZ procedures.

4.2.3.4. The auditors set up – for themselves – a plan of approach so as not to lose sight of the primary areas for attention.

4.2.4. Implementation:

4.2.4.1. The auditors conduct the audit in accordance with their plan of approach. Should they wish, it can be decided to check something –during the audit - in another department.

4.2.4.2. The auditors are free to subject everything to that audit that they consider necessary, over and above the primary points.

4.2.5. Reports and subsequent discussion:

4.2.5.1. The auditors provide a written report immediately following the audit to the QA manager. The QA manager and/or the auditors can also request a subsequent discussion on the findings. This concludes the auditor's task in the audit.

4.2.5.2. The QA manager determines whether any possible faults are an NC or a point for attention.

4.2.5.3. The QA manager drafts a formal audit report (of which the auditors' report is generally a part) for management (with all parties involved cc-ed).

4.2.5.4. The audit report includes at least the following:

4.2.5.4.1. audit details: name of the department/process, persons audited and date of the audit

4.2.5.4.2. any separate approach/reason and the general impression of the auditors

4.2.5.4.3. NC's with corrective actions, party involved in the problem. In principle, a NC should be rectified within three months, at the responsibility of the team leader/manager, unless the fault is of such a serious nature that correction is required earlier.

4.2.5.4.4. recommendations/points for attention

4.2.5.4.5. approval/rejection by management

4.2.6. Assessment by management
Management assesses the results of the audit. If necessary/desired, management will decide on the recommendations/points for attention and link this to the formal audit report. Management will initial the report by way of approval (along with comments, where necessary) and return it to the QA manager.

4.2.7. The QA manager's actions:
The QA manager includes all of the corrective measures from the formal audit report in a **Corrective Action Request.** and sends it electronically to the party involved in the problem.

4.2.8. Linking back to the party involved in the problem (generally the team leader/manager):
The party involved in the problem for an issue in the formal audit report informs the QA manager, using the received Corrective Action Request and within the time set therein, about what has been done in regard to the identified fault, what the root cause was and whether the corrective measure has been effective. If necessary, the QA manager will verify this.

Time required by the internal auditor:

Preparation:	max. 3.0 hours
Preparatory discussions:	max. 0.5 hours
Audit:	max. 2.5 hours
Reporting:	max. 1.5 hours

Subsequent discussions:	max. 0.5 hours
Total:	**max. 8.0 hours**

Change Record

Revision	Change Description	Date	Initiated By:

Originator:	Approved:	Date:
Associated Part No N.A. 101 & 201	Approved:	Date:

1.0 PURPOSE

This procedure specifies how documents are managed. This includes the method to be followed in creating, amending and releasing documents that are a part of the quality system.

2.0 SCOPE

2.1. The quality system is subdivided into:

2.1.1. The quality handbook:

A	Quality handbook	contains outlines of policy, organization and (process) management
B	Quality handbook procedure	contains instructions focusing on departments.

2.1.2. The departmental instructions folders: contain the work instructions and outlines for the registrations required for the direct activities within a given department. If a storage location, a deadline or any other detail is pertinent to a document, then this is stated in the instructions. Obvious deadlines and/or aspects, or ones that are required by law, do not also need to be included.

Note: The quality handbook part A contains general information and can be perused by anyone, including external parties.

Note: The quality handbook part B, including procedures and the instruction folders for the various departments, contains company-specific information and thus is not suitable for access by third parties.

Note: As of 01 June 2003, the intranet version will always be the valid version.

3.0 PROCEDURE

3.1. On the Quality handbook:

3.1.1. Every employee may, after consulting with the employee(s) involved, submit a proposal in writing or verbally to supplement or amend the Quality handbook (both parts A and B) to the KAM (Quality, Occupational Health and Safety and the Environment) manager.

3.1.2. The KAM manager determines, in consultation with the submitter and the manager concerned – who is responsible for the procedure - whether the proposal will be developed and who will prepare the draft,

3.1.3. The KAM manager introduces, in consultation with the submitter and the author, any changes to the draft procedure and sets the draft out in the standard formulation code.

3.1.4. The KAM manager releases the document by publishing it on the intranet.

3.1.5. Once published, the KAM manager announces, on the same day (at least to the manager concerned, but normally to all managers and team leaders and/or everyone at Scion), that the quality handbook has now been amended.

3.1.6. Managers and team leaders are responsible for passing the announcement on within departments, or for implementing the supplement/amendment.

Note: Copies (paper or digital) of parts of the quality handbook are not 'checked copies' and fall under the full responsibility of the person making the copies. Should anything be amended or deleted, the maker of the copies must delete them.

3.2. On Departmental folders (work instructions):

3.2.1. Every employee may, after consulting with the employee(s) involved, submit a proposal in writing or verbally for a new instruction or the amendment to an existing instruction to their team leader.

3.2.2. The team leader determines, in consultation with the submitter and (where applicable, at his discretion) the KAM manager, whether the proposal will be developed and who will prepare the draft version of the instruction.

3.2.3. The team leader introduces, in consultation with the submitter and the author, any changes and sets the draft out in the standard formulation code.

3.2.4. The team leader releases the instruction or returns the draft instruction to the author for improvements, after which it can be released.

3.2.5. Upon releasing the instruction, the team leader files the new instruction. When amended instructions are released, the old copies of the instruction are destroyed by the team leader.

3.3. Manual changes:

3.3.1. Changes to instructions that need to be implemented with immediate effect can be introduced manually by the team leader concerned. The team leader authorizes the change by entering the date and his initials.

3.3.2. The team leader must make the change officially, as outlined above, within 4 weeks.

4.0 MANAGEMENT AND ADMINISTRATION:

4.1. On the Quality handbook:

4.1.1. The KAM manager:

4.1.1.1. updates the content of the quality handbook when a document has to be added, amended or removed, in accordance with the last version agreed to with the manager concerned.

4.1.1.2. manages all original documents contained in the quality handbook.

4.2. On Departmental folders (work instructions):

4.2.1. The team leader is responsible for:

4.2.1.1. managing the content of the departmental instructions

4.2.1.2. the presence, in the department, of the complete and most up to date departmental instructions

4.2.1.3. the actual collection and destruction of all expired pages in the departmental instructions

4.2.1.4. updating the contents of the instruction folder if an instruction is added, amended or removed

4.2.1.5. managing all original instructions that are applicable within his department

4.2.1.6. managing the changes, either by keeping the earlier versions or by detailing the changes

4.3. Standard form layout

4.3.1. At Scion, there is a preferred, though not compulsory, layout for forms for work instructions.

4.3.2. The preferred classification follows the layout of the quality handbook procedures as much as possible.

It is arranged as follows:

A	**B**	**D** **E**
A	**C**	**F** **G** **H**

A.	Space for the logo and/or the Scion name thus adhering to the 'brand instructions' of Scion.
B.	Space for stating the type of document or department such as:

	QUALITY HANDBOOK
	QUALITY HANDBOOK PROCEDURES
	WORK INSTRUCTION and the NAME OF THE DEPARTMENT
C.	Space for stating the title of the document, such as DOCUMENT MANAGEMENT
D.	Space for stating the document code (see codes below).
E.	Space for stating the page numbering and the total number of pages in the document. (does not apply to .htm pages on the intranet)
F.	Space for stating the date upon which the (new or amended) document takes effect.
G.	Space for stating the document revision number. The word "English" can be added when it concerns an English translation of a revised document under the same doc. no.
H.	Space for the initials of the person that released the document. (does not apply to .htm pages on the intranet)

4.3.3. All **Word documents** are typed using a word processor, in which the **font Arial 11 pt** is preferred. If a document is amended, the amended text should be marked with a "*" or a "|" in the left-hand margin.

4.3.4. All **intranet (.htm) texts** in the quality handbook are in the font **Verdana Size 2**. Amendments are listed for each version in '+++ *Procedure change information* +++', at the end of the document. This applies as of 01-Jun-2003.

4.4. Quality handbook codes

4.4.1. The chapters in Quality handbook part A are made up of four parts, namely:

4.4.1.1. The letters KHA, which is the general designation for a Quality handbook part A (Kwaliteitshandboek deel A) chapter.

4.4.1.2. The chapter number preceded by 'CH' (=chapter)

4.4.1.3. Two numbers, indicating the section within the chapter.

4.4.1.4. A possible addition in order to specify whether the procedure applies to:

Business Unit	No further specifications
Business Unit Instruments	\I or \i

4.5. Quality handbook procedures' codes

4.5.1. The document number of a procedure is made up of four parts, namely:

4.5.1.1. The letters IKZ (Interne Kwaliteitszorg – Total Quality Management), which is the general designation for a procedure.

4.5.1.2. Letters that indicate which department has initiated this procedure or the department/process to which this procedure is most applicable. These departments/processes are:

DIR	Board of directors and management
P&O	Personnel and Organization
KWA	Internal Quality Audit (Interne Kwaliteitszorg)
R&D	Research and Development
PRO	Production
F&A	Finance & Administration
IT	Information Technology
LOG	Customer Services (Logistics)
INK	Materials Management (Procurement)
MAR	Marketing
THD	Technical Helpdesk
ARB	Managing working conditions
MIL	Environmental management

4.5.1.3. Two numbers, indicating the sequential number

4.5.1.4. Possible addition to specify whether the procedure applies to:

Business Unit	No further specifications
Business Unit Instruments	\I or \i

4.6. Work instructions' codes

(N.B. This applies to instructions dated after 03 April 1998)

4.6.1. The document number of an instruction is made up of 3 parts, namely:

4.6.1.1. Letters, indicating which department this instruction applies to. These departments are:

DIR	Board of directors and management
P&O	Personnel and Organization
KWA	Internal Quality Audit (Interne Kwaliteitszorg)
R&D	Research and Development
PRO	Production
F&A	Facility & Administration
IT	Information Technology
LOG	Customer Services (Logistics)
INK	Materials Management (Procurement)
MAR	Marketing
THD	Technical Helpdesk
ARB	Managing working conditions
MIL	Environmental management

4.6.1.2. The costs' location number in terms of the costs of the (sub) department.

4.6.1.3. Numbers, indicating the sequential number

4.6.2. In this way, a document number is assigned to a work instruction, making it clear:

4.6.2.1. that this is a work instruction (given that 'KHA' or 'IKZ' is absent),

4.6.2.2. which department is concerned (by naming the department and the unique costs' location number).

4.7. Structure of a document

4.7.1. As regards the chapters in the Quality handbook (part A), the following topics must be included, where applicable:

4.7.1.1. Policy

4.7.1.2. Organization

4.7.1.3. Implementation

4.7.2. As regards the Quality handbook **Procedures** (part B) and the **Work instructions**, the following can be included (where applicable) in a document:

4.7.2.1. Introduction

4.7.2.2. Purpose

4.7.2.3. Definitions

4.7.2.4. References

4.7.2.5. Area of application

4.7.2.6. Procedure(s)

4.7.2.7. Resources and forms to be used

4.7.2.8. re 1. The introduction contains relevant information that the employee requires to understand the outlined procedure and properly implement it.

4.7.2.9. re 2. In the purpose, it is stated what the document is intended for and why it is being included in the Quality system.

4.7.2.10. re 3. Under definitions, any specific terms must be defined so as to avoid ambiguity.

4.7.2.11. re 4. Under references, references are made to relevant documentation.

4.7.2.12. re 5. The area of application states where the document is applicable.

4.7.2.13. re 6. Under procedure, all actions and activities are outlined.

4.7.2.14. re 7. A summary of all information, materials, forms, etc. used..

Change Record

Revision	Change Description	Date	Initiated By:

scion INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **REJECTED PRODUCTS**	KWA-05	Rev.
		Date 11/5/15	
		Page 1 of 2	

Originator:	Approved:	Date:
Associated Part No N.A. 101 & 201	Approved:	Date:

1.0 PURPOSE

Scion only wants to deliver approved products to its customers. For this purpose, it ensures that rejected products are controlled.

2.0 RESPONSIBILITIES

The team leader of the department where a product undergoes a process (such as manufacturing, internal transportation, storage, packing or readying for shipping) is responsible for a rejected, broken or in any other way imperfect product being identified.

The team leader of the department concerned is responsible for ensuring that the relevant ('rejected') products are removed from the system or are returned to the previous department in the chain or are offered (in an accountable manner) as waste.

3.0 PROCEDURE

Due to the large number of products, and the resulting potential number of types of 'rejection', a fixed procedure is now in place.

Scion uses the following identification methods:

Identification method	**Description/explanation**
Fixed location (with inscription):	Products are placed in an identifiable location (with an inscription) where only 'rejected' products may be placed.
Labeled container:	Products are placed in a container in which only 'rejected' products of the type indicated on the label may be placed. The container does not have to be located in a specific location.
Turned into scrap/essential component removed/visible	The product is marked (visually) in such a manner that (irrespective of where it is located) it will never end up in the

scion INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **REJECTED PRODUCTS**	KWA-05	Rev.
		Date 11/5/15	
		Page 1 of 3	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

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Turned into scrap/essential component removed/visible	The product is marked (visually) in such a manner that (irrespective of where it is located) it will never end up in the

SCION INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **Preventative And Corrective Measures**	KWA-08	Rev.
		Date 11/5/15	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

Scion aims to continuously improve. This is important for its customers as well as for the company in Middelburg, enabling it to present itself as a center of excellence within Scion.

Making corrections and learning from mistakes as well as encouraging preventative measures all contribute directly to achieving continuous improvement.

This procedure is a compulsory procedure within ISO-9001:2008 and has deliberately been kept general in nature as various systems within

Scion already contain these elements.

2.0 RESPONSIBILITY

Team leaders and managers are responsible for encouraging initiatives that lead to corrective and preventative measures.

3.0 PREVENTATIVE AND CORRECTIVE TOOLS:

There are various systems within Scion that can serve as a tool or a reason for preventative and/or corrective measures:

- design and development procedures
- complaints procedure, escalations
- a production problem or a hotspot
- reports and reviews
- performance charts
- product line team (PLT)
- opportunity board meetings
- internal and external audits (products(TüV)/Corporate/Milieu/Arbo/Financieel/ISO-9001(BVQI)/GLP-compliance, etc)

- PECO-ECO, the change procedure for products
- a creative idea proposed by someone (as a result of 'creative dissatisfaction', for example)
- SOS, signaling undesired situations of any nature
- near accident or incident report
- *etc.*

Depending on the impact and scope (such as complexity, expense and/or >100 hours spent) of a measure, a plan of approach for the project might be required - see the relevant project procedures.

In the event of a limited impact or smaller scope (at the judgment of the relevant manager/team leader), the rest of the chain is investigated and/or asked to provide approval, generally through a task team – see the relevant procedures.

If a system or improvement procedure is not outlined, then approval is requested through a controlled trial (for example, through a draft procedure/instruction or by a trial on a small scale/in a test environment) from the managers concerned for changes to working methods and instructions. A change sometimes also requires the application of one of the aforementioned systems (such as PECO-ECO or SOS), which can result in the drafting of a new instruction or procedure.

NB Trials only result in sellable products if the products have passed the regular release test(s).

Change Record

Revision	Change Description	Date	Initiated By:

SCION INSTRUMENTS	Process Work Instruction Radiation Safety Manual Introduction Of New Employees	P&O-05	Rev.
		Date 11/5/15	
		Page 1 of 3	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

Systematically integrating new employees into the organization by means of an introductory program.

2.0 SCOPE

This procedures applies to Scion Instruments authorized users who perform semi-annual leak testing, ship ECDs to customers, and receive ECDs from a customer.

3.0 DEFINITIONS AND ABBREVIATIONS

3.1. Employees are taken to include:

3.1.1. employees with a permanent or temporary employment contract
3.1.2. temporary employment agency workers
3.1.3. interns and final-year students.

3.2. The introduction consists of two main parts:

3.2.1. becoming acquainted with the company
3.2.2. becoming acquainted with the job, otherwise known as induction.

3.3. Becoming acquainted with the company is taken to include:

3.3.1. becoming familiar with the nature of the company
3.3.2. the organizational set-up
3.3.3. the rules that generally apply

3.4. Becoming acquainted with the job is taken to include:

3.4.1. becoming familiar with one's superiors and colleagues in the department
3.4.2. becoming familiar with employees in other departments with whom one will have job-related contact
3.4.3. the actual induction, which involves learning or practicing the actual work.

Note: NB: see IKZ-IT-08 to be able to consider in good time whether IT and communication resources are required.

4.0 INTRODUCTORY PROGRAM:

Where relevant, an introductory program is drawn up by the superior to ensure that things run as smoothly as possible. This introductory program is discussed by the superior with the new employee on the latter's first day at work.

HR sends the letter of appointment, the terms and conditions of employment (P&O procedures and safety regulations) and the organizational chart to the new employee. This does not apply to temporary employment agency workers, interns or final-year students.

4.1. The first day:

1.	Welcome by HR or an HR delegation.
1.1	Welcome
1.2	Dealing with administrative matters and discussing various regulations and policies.
1.3	Explanation of the organizational chart.
2.	Welcome by the employee's superior
2.1	Becoming acquainted with colleagues and the work environment.
2.2	Guided tour.
2.3	Explanation of the departmental rules and the regulations concerning safety in particular. NB. See IKZ-ARB-07 for the working method with regard to the Introduction to Health and Safety and the Environment – HSE - at Varian.
2.4	Discussion of the induction and training program.
2.5	Initial explanation, where necessary, of the work itself.

3. Announcement

3.1 HR announces on the intranet that the new employee has begun work.

4.2. The induction period:

4.2.1. Induction, following training courses, traineeship and similar activities where necessary.
4.2.2. Becoming acquainted with job-related contacts.

4.3. Test times:

4.3.1. In the first week:

4.3.1.1. Once the VGM document has been read, the VGM checklist is used by the superior to test the employee's required knowledge of HSE.

4.3.2. Before the end of the trial period:

4.3.2.1. Evaluation by the superior and/or together with HR of the new employee, during which it is formally established whether the trial period can be successfully concluded.

4.3.3. Before the conclusion of the first year:

4.3.3.1. Evaluation by the superior and/or together with HR of the new employee to determine whether the temporary employment arrangement can be converted into a indefinite term contract, or a temporary contract needs to be formed again.

4.3.3.2. In addition, periodic assessment interviews are held, as outlined in IKZ-P&O-06. Test times 2 and 3 do not apply to temporary employment agency workers, interns or final-year students.

Change Record

Revision	Change Description	Date	Initiated By:

scion INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **Medical Check-Ups**	P&O-07	Rev.
		Date 11/6/15	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

This procedure outlines the initiation, registration and steps of the periodic check-ups for certain risk groups, and the written periodic occupational health examination, for which every employee can report.

2.0 RESPONSIBILITY

The Human Resources (HR) manager is responsible for initiating and announcing in good time the medical check-up and periodic occupational health examination.
Every employee is responsible for registering and reporting for the check-up.

2.0 PROCEDURE

2.1. HR announces on the noticeboards that a check-up is planned, and states how it is possible to register and then how employees are subsequently invited to attend.

2.2. Employees that wish to be checked indicate as such in good time and in the specified manner.

2.3. HR announces the date, location and time of the check-up in the specified manner.

2.4. In the case of the written periodic occupational health examination, HR distributes forms and these are returned to the occupational health and safety physician for evaluation.

2.5. Once they have been examined by the occupational health and safety physician, the results of the check-up are announced to the employee in writing or verbally.

The period check-up for certain risk groups entails:

Examination:	Once a year	Offered to employees performing the following duties:
Hearing	2	• Working with compressed air
Breathing	4	• Packaging using the Instapak system (Dispatch)
Eyesight	4	• Working in front of a computer monitor for more than 2 hours a day

Change Record

Revision	Change Description	Date	Initiated By:

SCION INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **Control Of Production Tools Using Preventative Maintenance**	PRO-05	Rev.
		Date 11/5/15	
		Page 1 of 1	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

Preventative maintenance is maintenance undertaken in order to prevent problems arising during production.

2.0 RESPONSIBILITIES

The team leaders are responsible for the prescribed maintenance of production tools.
Maintenance can be contracted out to third parties (both internal and external ones), but the team leader still bears responsibility.
Every user of production tools is responsible for correct usage and must immediately report any breakdowns to his or her team leader so that suitable measures can be taken.

3.0 PROCEDURE

3.1. Every production tool is registered by department in a summary of approved operational equipment. They can be divided into two categories, namely Preventative (P) and Corrective (C).

3.1.1. Production tools identified as P are preventatively maintained.

3.1.2. Production tools identified as C are repaired if repairs are required.

3.2. Every production tool that is preventatively maintained bears a sticker upon which the date of the next scheduled service is stated.

3.3. The frequency of maintenance is determined by the team leader. This frequency can be adjusted based on the results of the previous service or in line with past experience with similar equipment.

3.4. Registration and preventative maintenance can be internally contracted out to Production Engineering (see IKZ-PRO-07). The details of service work must be retained for at least 4 years.

Change Record

Revision	Change Description	Date	Initiated By:

scion INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** Bills of Materials (BOMs)	PRO-06/i	Rev.
		Date 11/6/15	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

This procedure outlines the way in which the Bill Of Materials (BOM), also called a parts list, is created or amended in a structured and properly documented manner.

2.0 RESPONSIBILITIES

2.1. A BOM can be divided up into 4 parts, with a different department bearing responsible for each one.
The breakdown is as follows:

1. Materials : R&D
2. Purchase price of the article : Procurement
3. Production hours : Production Manager
4. Hourly rate : Controller

3.0 PROCEDURE

3.1. Materials:
As regards new products, a BOM is created under the authority of the project leader. He is also responsible for the composition and structure of the BOM and the routing for production. The Documentation department ensures it is entered into the computer system.
Amendments to existing BOMs are dealt with in accordance with the VTW/BTW procedure (see IKZ-R&D-06\I).

3.2. Purchase price of the article:
In the case of products purchased new, the cost price is determined for each article via the BOM (see IKZ-INK-07), after which it is entered into the computer.
All changes to prices are immediately entered to the current cost price as soon as Procurement learns of the change from a supplier.

3.3. Production hours:
In the case of new products, an estimate is made of how many hours are needed for a given product. This calculation is made by consultation between the Production manager and the team leader or team leaders of the section where the product is manufactured. After the zero or first

series of this product, a definitive number of hours is set. Production enters the number of production hours into the computer.
The production hours are recalculated annually and amended where necessary or amended as a result of a product change.

3.4. Hourly rate:
Once the budgets for the following year have been definitively approved by the General Manager, the Financial Administration will calculate a new hourly rate for the Production department.□Once approval has been received from the Controller, this hourly rate is then fixed for that year.
Once approval has been received from the Controller, this hourly rate is then fixed for that year.

3.5. Exceptions:
There is an exception in the case of **one-off** BOMs. These BOMs are created for complete systems in production, known as special numbers.
The team leader of the department where such a system is being made is responsible for this BOM - both for creating it (Materials and production hours) and for entering it into the computer system.
The standard hourly rate will also apply to this.

3.6. Cost price:
There are two types of cost price, namely:

3.6.1. current cost price

3.6.2. standard cost price

3.7. The current cost price is the cost price of an article which can be immediately amended when required, such as when the purchase price changes.

3.8. The standard cost price is the cost price used by Production, for example. This cost price is adjusted once per quarter. The new standard cost price is approved by the Controller.

Change Record

Revision	Change Description	Date	Initiated By:

scion INSTRUMENTS	**Process Work Instruction** **Radiation Safety Manual** **Checklist For New Equipment And New Products In The Department**	PRO-10	Rev.
		Date 11/6/15	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A. 101 & 201	Approved:	Date:	

1.0 PURPOSE

This procedure serves as an aid for team leaders when the department receives new equipment (or equipment acquired from another department), as an investment, and/or new products need to be produced, as manufactured articles, so as to allow fluid incorporation of these requirements in the organization.

2.0 RESPONSIBILITY

The Production Team Leader is responsible in the specified cases for checking and organizing as quickly as possible all of the listed points with the departments/employees concerned.

The Production Team Leader ticks off the items on the checklist below, where appropriate, by filling in a 'date completed' when a certain point has been carried out. Once all that is required has been seen to, this checklist does not then have to be retained.

Checklist for new equipment and new products:

New equipment/investment	Purpose	Date completed or n/a
Report equipment to PE	Obtain TDno. (TDno.=_____)	
	Maintenance: state whether corrective or preventative (calibrating frequency and specs)	
	State maintenance for NEN-3140	
If it is a radioactive source	Report to Logistics for inclusion in sources file	
	Placing the ECD work instruction (see IKZ-ARB-03)	
Release for the process	*Once the above actions have been completed:* Release/acceptance for introduction to production.	
Investment (obtained via AR)	Assign investment number (from the next three-monthly overview from Finance) to the	

	investment.	
New product (manufactured article):	**Purpose**	**Date completed or n/a**
Full transfer	Has everything been received from R&D? See release action list/checklist from R&D for the product concerned.	

Change Record

Revision	Change Description	Date	Initiated By:

Scion Instruments Austin, TX	**Process Work Instruction Radiation Safety Manual FORM 1** Package Survey Form		Initial
		Date: 11/4/15	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A.	Approved:	Date:	

1.0 PURPOSE

This Form is a complement to SOP 4, Surveying Pacakages Containing Radioactive Materials.

2.0 SCOPE

This procedure applies to the RSO, the backup RSO, and employees who receive, store, and/or ship ECD's.

3.0 DEFINITIONS AND ABBREVIATIONS

- Radiation Safety Officer (RSO) - The on-site Scion employee who is identified on the Scion radioactive materials license as the RSO. The RSO has statutory responsibilities as identified in the radioactive materials license and in Texas code 25 TAC §289.252(f).

4.0 CONTROL AND DISTRIBUTION OF THIS DOCUMENT

This procedure is a controlled document under the Radiation Safety Manual, and all changes must be approved by the RSO.

NC	Initial Release	11/4/2015	T. Brandon

Typical Backgound: ____________

Date	Surveyor	Package Description	Instrument Model #	Instrument Serial #	Results	Notes

SCION INSTRUMENTS Austin, TX	**Process Work Instruction** **Radiation Safety Manual** **SOP 2** Receiving and Storing ECD Devices		Initial
		Date:	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A.	Approved:	Date:	

1.0 PURPOSE

This procedure describes a process for regulatory compliance, reducing the risk of radiation exposure or contamination from receiving and storing Ni-63 foils, contained in ECD cells, contained in ECD detectors, contained in "black box" containers, contained in UN2911 packages.

2.0 SCOPE

This procedure applies to the RSO, the backup RSO, and employees who receive, store, and/or ship ECD's.

3.0 DEFINITIONS AND ABBREVIATIONS

- Radiation Safety Officer (RSO) - The on-site Scion employee who is identified on the Scion radioactive materials license as the RSO. The RSO has statutory responsibilities as identified in the radioactive materials license and in Texas code 25 TAC §289.252(f).

4.0 CONTROL AND DISTRIBUTION OF THIS DOCUMENT

This procedure is a controlled document under the Radiation Safety Manual, and all changes must be approved by the RSO.

5.0 PROCEDURE

5.1. The RSO and/or the backup RSO control(s) the inventory below licensed limits, discouraging uncontrolled shipments to the Austin, TX, site.

5.2. Inspect the package for damage (crushed, wet, etc.?). A survey of an undamaged UN2911 package is not required. No test of contamination is required.

5.3. If the package is damaged, notify the RSO, if available. If unavailable, put on gloves, tag the package as damaged, and store the package in the lockable cabinet for packages of devices.

5.4. Open the outer package following shipper's instructions, if provided.

5.5 Open the inner package and verify

5.5.1 Contents match the packing slip.

5.5.2 The package contains a leak test with a date no more than 6 mo. old. Record including date received.

5.5.3 The package contains a quality certification. Record including date received.

5.5.4 The package contains an ECD. Record serial number without opening "black box" if possible. Record, including date received.

5.5.5 If there are discrepancies, errors, or omissions, notify the RSO. If the RSO is not available; tag, bag, and store the package in the lockable storage cabinet label: Caution Radioactive Material.

5.6 Amend the radioactive inventory, including information recorded above.

NC	Initial Release	9/13/2015	G. Brown

SCION INSTRUMENTS Austin, TX	**Process Work Instruction** **Radiation Safety Manual** **SOP 4** Surveying Packages Containing Radioactive Material		Initial
		Date: 11/4/15	
		Page 1 of 2	
Originator:	Approved:	Date:	
Associated Part No N.A.	Approved:	Date:	

1.0 PURPOSE

This procedure describes a process for surveying packages that have been prepared for shipment.

2.0 SCOPE

This procedure applies to the RSO, the backup RSO, and employees who receive, store, and/or ship ECD's.

3.0 DEFINITIONS AND ABBREVIATIONS

- Radiation Safety Officer (RSO) - The on-site Scion employee who is identified on the Scion radioactive materials license as the RSO. The RSO has statutory responsibilities as identified in the radioactive materials license and in Texas code 25 TAC §289.252(f).

4.0 CONTROL AND DISTRIBUTION OF THIS DOCUMENT

This procedure is a controlled document under the Radiation Safety Manual, and all changes must be approved by the RSO.

5.0 PROCEDURE

5.1. Only persons trained in accordance with Department of Transportation (DOT) regulations 49 CFR shall be permitted to ship or open packages containing electron capture device(s) (ECD) devices.

5.2. Packages containing instruments with radioactive sources shipped as excepted packages and labeled UN2911 are **not** required to be surveyed upon receipt.

5.3. A representative sample of packages being offered for transport is required to be surveyed and wiped for contamination, and the results documented. The US DOT does not define what constitutes a representative sample; however, at least one package per shipment lot.

5.4. Survey Procedures

5.4.1. Put on gloves to prevent hand contamination;

5.4.2. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop and notify the Radiation Safety Officer (RSO).

5.4.3. Monitor the external surfaces of a labeled package for radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

5.5. The monitoring required by Item 1 above shall be performed as soon as practicable after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three (3) hours from the beginning of the next working day. **Packages, which cannot be surveyed immediately, must be secured in a lockable area until the designated individuals can perform a survey on it.**

5.6. Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on container).If anything is other than expected, stop and notify the RSO.

5.7. Maintain records of receipts as well as serial number of enclosed ECD device (without opening the ECD case if possible), operating instructions on disk, leak results, and quality certification on the package receipt form.

5.8. The final carrier, the Nuclear Regulatory Commission (NRC), and the Texas Department of State Health Services (DSHS) Radiation Control (RC) Department shall be immediately notified by telephone and shall confirm the initial contact within 24 hours by overnight letter or fax to the NRC and Texas DSHS RC external radiation levels exceed the limits of 49 CFR 173.421 (0.5 mrem/hr.).

NC	Initial Release	11/4/2015	T. Brandon

Scion Instruments Austin, TX	**Process Work Instruction** **Radiation Safety Manual** **SOP 1** Radiation Safety Training Procedure	Initial Date: Page 1 of 3

Originator:	Approved:	Date:
Associated Part No N.A.	Approved:	Date:

1.0 PURPOSE

This procedure defines the radiation safety training requirements for the RSO, the backup RSO, and employees who receive, store, and ship packages containing electron capture devices (ECD's).

2.0 SCOPE

This procedure applies to the RSO, the backup RSO, and employees who receive, store, and/or ship ECD's.

3.0 DEFINITIONS AND ABBREVIATIONS

- Radiation Safety Officer (RSO) - The on-site Scion employee who is identified on the Scion radioactive materials license as the RSO. The RSO has statutory responsibilities as identified in the radioactive materials license and in Texas code 25 TAC §289.252(f).

4.0 CONTROL AND DISTRIBUTION OF THIS DOCUMENT

This procedure is a controlled document under the Radiation Safety Manual, and all changes must be approved by the RSO.

5.0 PROCEDURE

5.1. The RSO and the backup RSO shall attend a 40-hour RSO course given by an outside training provider. Successful completion of this course must be proven by passing an exam and receiving a certificate.

5.2. Employees, who use and handle packages of radioactive materials in the Scion Instruments ECD receiving, inspection, and shipping areas, shall attend a 2-hour radiation safety training course for Authorized Users provided by an individual with previous RSO experience. Successful completion of this course must be proven by passing an exam (20 questions; 70% required) and by signing an attendance roster.

5.3. Employees shall share the Scion belief that the radioactive Ni-63 source in the ECD will neither emit radiation capable of penetrating the housing nor degrade so long as it is shipped, received, inspected, stored, and reshipped and stored as intended. Users must follow instructions for compliance and safety.

5.4. Employees will receive instruction in the following subjects:

5.4.1. Radiation Fundamentals

5.4.2. Types of Radiation

5.4.3. Radioactive Decay

5.4.4. Radiation Units (Activity, Exposure, Contamination)

5.4.5. Biological Health Effects

5.4.6. Regulatory Requirements (RHB, NRC, DOT, IATA)

5.4.7. Measurement and Control

5.4.8. ALARA Principles (Time, Distance, Shielding)

5.4.9. Handling Radioisotopes (Ni-63 Sealed Sources)

5.4.10. Radiation Safety Work Practices/Procedures

5.4.11. Contamination Control

5.4.12. Contamination Survey Techniques and Wipe Leak Tests

5.4.13. Locked Storage and Labeling of Licensed Radioactive Materials and Storage Areas

5.4.14. Posting Requirements for Licensed Radioactive Materials Use and Storage Areas

5.4.15. "Caution - Radioactive Materials" Signs and Labels

5.4.16. Personnel Monitoring (Unavailable and Not Required for Ni-63)

5.4.17. Recordkeeping

5.4.18. Emergency Procedures

5.4.19. Receiving and Packaging, Labeling, and Shipping of Licensed ECD Devices

5.4.20. Radioactive Waste Disposal Procedures—Don't do it at Scion

5.4.21. Pregnant radiation worker declaration—Unnecessary at Scion

5.4.22. Radiation worker rights and responsibilities

5.5. Employees who are Authorized Users will be provided initial training before their first use or handling of radioactive materials, and refresher training on an annual basis. All in-house training shall be documented on the Scion Instruments employee training sign-in form. The record shall include the trainer's name, training date, attendees' names and signatures, and course outline.

5.6. Employees involved in packaging, labeling, and shipping of ECD devices must complete DOT hazardous materials training as well as IATA training.

5.5.1 DOT HAZMAT refresher training is required every 3 years.

5.5.2 IATA refresher training is required every 3 years.

5.5.3 Add one-time training in operator manual for Scion ECD model 02-001972-02.

5.5.4 Add one-time training in operator manual for RadEye B20 Multi-Purpose Survey Meter or equivalent

Change Record

Revision	Change Description	Date	Initiated By:
NC	Initial Release	9/13/2015	G. Brown

SCION INSTRUMENTS Austin, TX	**Process Work Instruction Radiation Safety Manual SOP3** Shipping Scion ECD Devices		Initial
		Date:	
		Page 1 of 3	
Originator:	Approved:	Date:	
Associated Part No N.A.	Approved:	Date:	

1.0 PURPOSE

This procedure describes a process for regulatory compliance, reducing the risk of radiation exposure or contamination from shipping Ni-63 foils, contained in ECD cells, contained in ECD detectors, contained securely and tightly in ECD cases, contained in UN2911 packages.

2.0 SCOPE

This procedure applies to the RSO, the backup RSO, and employees who receive, store, and/or ship ECD's.

3.0 DEFINITIONS AND ABBREVIATIONS

- Radiation Safety Officer (RSO) - The on-site Scion employee who is identified on the Scion radioactive materials license as the RSO. The RSO has statutory responsibilities as identified in the radioactive materials license and in Texas code 25 TAC §289.252(f).

4.0 CONTROL AND DISTRIBUTION OF THIS DOCUMENT

This procedure is a controlled document under the Radiation Safety Manual, and all changes must be approved by the RSO.

5.0 PROCEDURE

5.1. Receive an address for a US customer.

5.2. Take an undamaged package from the lockable storage cabinet labeled: Caution Radioactive Material.

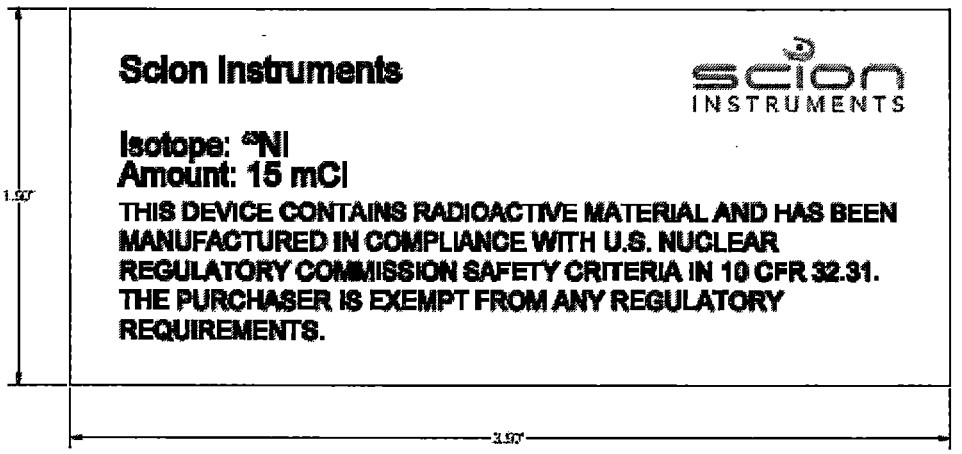
5.3. Verify the package contains:

5.3.1 a leak test with a date no more than 6 mo. old. Record including date shipped.

5.3.2 a quality certification. Record including date shipped.

5.3.3 an ECD. Record serial number and date shipped.

5.3.4 A " Radioactive Material" label on the inner container (ECD case). Record.



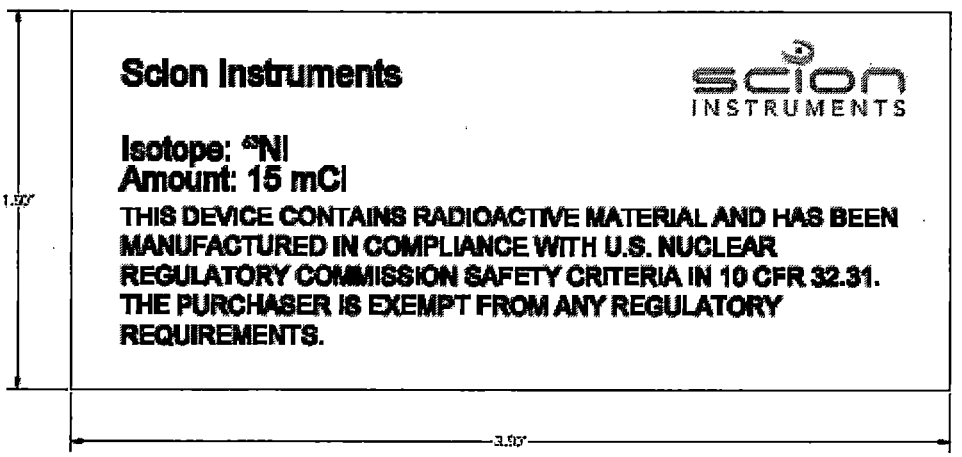
5.3.5 An operator's manual. Record.

5.3.6 Outer dimensions not less than 4 inches by 4 inches.

5.4 Notify the RSO if there is anything unusual about the package contents.

5.5 Reseal the package. The package must be a strong, tight package so that there will be no leakage of radioactive materials under conditions normally incident to transportation.

5.5.1 The outside of the package must be labeled "Radioactive Material"



5.5.2 The outside of the package must be marked "UN2911" inside the red hash marks of the IATA label.

5.5.3 Replace any original packing slip, if appropriate, and reseal. Record.

5.5.4 Change the Scion address to the US customer address. Record.

5.6 Measure the radiation level at 4 inches (10 cm) from all six sides of the package. Record. Must not exceed 0.5 mrem/hr. Record typical background and reading.

5.7 Notify a qualified shipper to pick up the package.

5.8 Amend the radioactive inventory, including information recorded above.

NC	Initial Release	9/13/2015	G. Brown

Autoriteit Nuclearie Veiligheid en Stralingsbescherming

> Retouradres Postbus 16001 2500 BA Den Haag

AANTEKENEN

Scion Instruments (NL) B.V.
t.a.v. de heer M.A. Westdorp
Stanleyweg 4
4462 GN GOES

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Stralingsbescherming
Aanvragen en Melden
Bezuidenhoutseweg 67
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2500 BA Den Haag
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Onze referentie
2015/0580-06

Bijlage(n)

Datum 25 september 2015
Betreft Vergunning Kernenergiewet

KERNENERGIEWETVERGUNNING VERLEEND AAN SCION INSTRUMENTS (NL) B.V. VOOR HET VERRICHTEN VAN HANDELINGEN MET RADIOACTIEVE STOFFEN

Verleend door:
DE MINISTER VAN INFRASTRUCTUUR EN MILIEU.

1. Het besluit

I. Vergunning
Aan Scion Instruments (NL) B.V. gevestigd te Goes wordt, krachtens artikel 29 van de Kernenergiewet en artikel 25 van het Besluit stralingsbescherming voor onbepaalde tijd conform de aanvraag vergunning verleend voor:

RADIOACTIEVE STOFFEN
Het verrichten van handelingen met radioactieve stoffen ten behoeve van het testen van en het inbouwen in detectoren en opslag binnen de locatie van Scion Instruments (NL) B.V., gelegen aan de Stanleyweg 4 te Goes, binnen de volgende omvang:

1. 200 ingekapselde bronnen nikkel-63 met een activiteit van maximaal 555 megabecquerel (MBq) per bron, en een gezamenlijke activiteit van 111 gigabecquerel (GBq).

II. Voorschriften
Aan deze vergunning worden de voorschriften verbonden, zoals opgenomen onder hoofdstuk 4 van deze beschikking.

III. Documenten

De volgende documenten maken deel uit van de vergunning:

- de op 8 juni 2015 ontvangen aanvraag;
- de op 28 juli 2015 ontvangen aanvullende informatie;
- de op 18 september 2015 ontvangen aanvullende informatie.

Bij strijdigheden prevaleert het meest recente document.

IV. Openbaarmaking en publicatie

De beschikking bevat milieu-informatie. Daarom wordt deze beschikking ingevolge artikel 8 van de Wet openbaarheid van bestuur actief openbaar gemaakt door publicatie van deze beschikking op de internetsite www.anvs.nl.

Van het verlenen van deze vergunning wordt tevens mededeling gedaan in de Staatscourant.

V. Inwerkingtreding

Gelet op het gestelde in artikel 20.5 van de Wet milieubeheer bepaal ik dat het besluit terstond in werking treedt. De reden hiervoor is dat Scion Instruments (NL) B.V. de productie overneemt van de fabriek in de USA. Deze fabriek gaat in oktober 2015 sluiten. Indien de vergunning niet terstond in werking zou treden ontstaat een productie hiaat.

2. De aanvraag, het toetsingskader en de beoordeling van de aanvraag

2.1. De aanvraag

De aanvraag heb ik op 8 juni 2015 ontvangen en heeft betrekking op een aanvraag voor het verrichten van handelingen met radioactieve stoffen.
In het bijzonder betreft het de volgende toepassingen:

- het testen van detectoren;
- het inbouwen in detectoren;
- het in opslag hebben.

Bij de aanvraag zijn de volgende documenten toegevoegd:

- Aanvraag vergunning.
- Copy BTW nummer en inschrijving KvK.
- Copy lektest certificaat + verklaring ISO classificatie.
- Produktie manual voor de assemblage van detector met de ingekapselde bron.
- Copy diploma stralingsdeskundige.
- Globaal meldingsformulier 2015.

Op 23 juli 2015 is verzocht om aanvullende informatie. Op 28 juli 2015 heb ik de volgende aanvullende gegevens ontvangen:

- Bijlage 1. aangepast vergunningaanvraag.
- Bijlage 2. uittreksel KvK om aan te tonen dat dhr. Van de Heuvel gemachtigd is deze aanvraag te ondertekenen.
- Bijlage 3. risico analyse.
- Bijlage 4. overeenkomst Coördinerend Stralingsdeskundige (Applus RTD);
- Bijlage 5. verslag beoordeling risicoanalyse door Coördinerend Stralingsdeskundige.
- Bijlage 6. verslag berekening stralingsniveaus aan de terreingrens.
- Bijlage 7. tekening gebouw met daarop aangegeven de plaats van handelingen.
- Bijlage 8. kadastrale tekening van de locatie.
- Bijlage 9 en 10. Werkinstructies.
- Bijlage 11. extra instructies/voorschriften voor nieuwe medewerkers ter ondertekening.

Op 16 september 2015 heb ik telefonisch voor de tweede keer verzocht om aanvullende informatie. Op 18 september 2015 heb ik de volgende aanvullende gegevens ontvangen:

- Mandaat Edwin Hollebrandse.
- Verklaring verzoek vervroegd in werking treden vergunning.

De aanvraag en de aanvullende informatieheb ik getoetst aan artikel 44 van het Besluit stralingsbescherming en artikel 2.6 van de Uitvoeringsregeling stralingsbescherming EZ en volledig bevonden.

2.2. Gevolgde procedure

Dit besluit is ingevolge artikel 29a van de Kernenergiewet en artikel 46 van het Besluit stralingsbescherming niet tot stand gekomen overeenkomstig de openbare voorbereidingsprocedure van afdeling 3.4 van de Algemene wet bestuursrecht. De op enig moment aanwezige hoeveelheid radionucliden in de bij de handelingen betrokken radioactieve stoffen is dermate beperkt dat op grond van artikel 46 van het Besluit stralingsbescherming afdeling 3.4 van de Algemene wet bestuursrecht niet van toepassing is.

2.3. Het toetsingskader

Aan het wettelijk kader van de stralingsbescherming, zoals vastgelegd in de Kernenergiewet en de onderliggende besluiten, liggen onder meer de drie principes van het stralingsbeschermingsbeleid ten grondslag, te weten: rechtvaardiging, ALARA en dosislimieten. Indien aan deze uitgangspunten niet wordt voldaan of indien aan de andere voorwaarden genoemd in artikel 39 van het Besluit stralingsbescherming niet wordt voldaan, wordt de vergunning niet verleend.

Rechtvaardiging houdt in dat een handeling die blootstelling aan ioniserende straling met zich meebrengt, slechts is toegestaan indien de economische, sociale en andere voordelen van de betrokken handeling opwegen tegen de gezondheidsschade die hierdoor kan worden toegebracht. Dit principe is vastgelegd in artikel 4, eerste lid van het Besluit stralingsbescherming.

Toepassing van ALARA (as low as reasonably achievable, ofwel zo laag als redelijkerwijs haalbaar) is de optimalisatie, gericht op beperking van de blootstelling aan ioniserende straling. In de wetgeving is het ALARA beginsel vastgelegd in artikel 31 van de Kernenergiewet en artikel 5 van het Besluit stralingsbescherming.

Dosislimieten vervullen een vangnetfunctie, indien het toepassen van rechtvaardiging en ALARA niet voldoende is om een bepaald beschermingsniveau te bereiken. De limietwaarden zijn vastgelegd in artikel 48, 49 en paragraaf 7.1 van het Besluit stralingsbescherming.

In gevallen waarin het onmiddellijk in werking treden van de vergunning noodzakelijk is, kan worden bepaald dat de vergunning terstond in werking treedt.

2.4 Bevindingen en overwegingen

Met inachtneming van paragraaf 2.3 heb ik de aanvraag getoetst aan artikel 39 van het Besluit stralingsbescherming. Geen van de daarin genoemde bepalingen staat vergunningverlening in de weg.

De in de aanvraag bedoelde handelingen zijn opgenomen in bijlage 1 van de Regeling bekendmaking rechtvaardiging gebruik van ioniserende straling.

Derhalve is sprake van gerechtvaardigde handelingen. Ook in de situatie die is beschreven in de aanvraag zijn deze handelingen gerechtvaardigd.

Uit de aanvraag is gebleken dat de aanvrager in voldoende mate stralingshygiënische maatregelen treft. Deze stralingshygiënische maatregelen en de aan de vergunning verbonden voorschriften bieden voldoende waarborgen, dat mensen, dieren, planten en goederen ten gevolge van de toepassing van radioactieve stoffen en/of ioniserende straling, zo weinig schade of hinder daarvan zullen ondervinden als redelijkerwijs mogelijk is.

Tenslotte is uit de aanvraag gebleken dat de dosislimieten voor leden van de bevolking en werknemers niet overschreden zullen worden.

2.5 Besluit

Op grond van het bovenstaande heb ik besloten om tot verlening van de vergunning over te gaan.

3. Definities

In deze vergunning gelden de onderstaande definities. Voor de overige termen en definities wordt naar de Kernenergiewet, het Besluit stralingsbescherming, en de onderliggende ministeriële regelingen verwezen.

- bergplaats:
  ruimte die uitsluitend wordt gebruikt voor de opslag van radioactieve stoffen;
- besmettingscontrole:
  controle van een oppervlak of een voorwerp, niet zijnde een ingekapselde bron, op radioactieve besmetting, waarbij het volgende in aanmerking wordt genomen:
  1. het oppervlak dat wordt afgewreven bedraagt circa 5 cm^2;
  2. de detectielimiet van de meting bedraagt voor alle nucliden maximaal 2 becquerel;
- broncertificaat:
  document van de producent van de ingekapselde bron waarin ten minste de activiteit, de nuclide, de gegevens van de capsule, de classificatie volgens Internationale standaard ISO 2919:1999 of recenter en het serienummer zijn vermeld;
- diploma ioniserende straling:
  diploma, certificaat, of ander getuigschrift afgegeven door een instelling als bedoeld in artikel 7f van het Besluit stralingsbescherming;
- intern transport:
  het verplaatsen van radioactieve stoffen, splijtstoffen of ertsen binnen een inrichting of een locatie, of tussen twee locaties binnen een inrichting, indien het vervoer onderworpen is aan regelgeving die op de inrichting van toepassing is en het vervoer niet via de openbare weg plaatsvindt;
- lek:
  een bron waarbij een afgewreven activiteit van meer dan 185 becquerel is vastgesteld;
- lektest:
  een controle van de behuizing van een radioactieve stof op radioactieve besmetting;
- radioactieve besmetting:
  een alfa besmetting van 0,4 becquerel of meer per cm^2 of een bèta/gamma besmetting van 4 becquerel of meer per cm^2;
- terreingrens:
  de begrenzing van de locatie, zoals aangeduid op tekening (bijlage 8 van de aanvulling d.d. 24 juli 2015 zoals bedoeld in bijlage 1.5 van de Uitvoeringsregeling stralingsbescherming EZ;
- voldoende instructie:
  instructie als bedoeld in de artikelen 15 en 16 van het Besluit stralingsbescherming, gericht op de handeling waarbij de werknemer betrokken is;

- waarschuwingssignalering en -teken:
  waarschuwingsbord en/of -teken dat in de in artikel 20, eerste lid, van het Besluit stralingsbescherming bedoelde situaties wordt aangebracht.

4. Voorschriften

I. Algemeen

1. Voor zover in de vergunning inclusief de voorschriften niet anders is bepaald worden de handelingen verricht overeenkomstig de in hoofdstuk 1.III genoemde documenten.

2. De ondernemer zorgt voor een met instemming van de in voorschrift II.1. genoemde deskundige vastgestelde procedure voor intern transport.

II. Organisatie

1. De ondernemer zorgt ervoor dat de handelingen plaatsvinden door of onder toezicht van een toezichthoudend deskundige of zijn plaatsvervanger die ten minste het diploma ioniserende straling niveau 5A of een gelijkwaardig diploma heeft behaald.

2. De ondernemer zorgt ervoor dat deze toezichthoudend deskundige schriftelijk gemandateerd is voor deze verantwoordelijkheid en dat deze zo vaak als nodig, en ten minste eenmaal per kalenderjaar, verantwoording aan hem aflegt door middel van een rapportage.

3. De taken, verantwoordelijkheden, bevoegdheden en de omvang van de aanstelling van de in artikel 10, lid 1 van het Besluit stralingsbescherming bedoelde coördinerend deskundige, zijn schriftelijk vastgelegd. In het geval dat de coördinerend deskundige niet in dienst is van de vergunninghouder, maar wordt ingehuurd, zijn bovengenoemde gegevens vastgelegd in een contract.

4. De ondernemer zorgt ervoor dat degenen die handelingen uitvoeren met/aan de ingekapselde bron ten minste het volgende niveau van stralingsdeskundigheid of een gelijkwaardig niveau hebben:

verwijderen uit, dan wel het plaatsen van de bronhouder met daarin de ingekapselde bron in het apparaat of de installatie:	niveau 5A
verantwoordelijkheid voor lektest en/of besmettingscontrole:	niveau 3.

III. Voorschriften met betrekking tot bronnen
A. Ingekapselde bronnen

Algemeen

1. Een binnenkomende zending met een ingekapselde bron wordt op een door de toezichthoudend deskundige aangewezen plaats uitgepakt en gecontroleerd. Indien de verpakking beschadigd is of wanneer tijdens het transport een incident heeft plaatsgevonden wordt de toezichthoudend

deskundige geïnformeerd die nadere instructies geeft. Wanneer de zending met een ingekapselde bron buiten werktijd wordt afgeleverd wordt de bron direct opgeslagen in een bergplaats en wordt de toezichthoudend deskundige hierover geïnformeerd.

2. Retouremballage (verpakkingsmateriaal) van een zending met een ingekapselde bron wordt, alvorens zij de locatie verlaat, zowel in- als uitwendig ontdaan van radioactieve besmetting. Aanduidingen of waarschuwingstekens van radioactiviteit hierop worden daarna verwijderd of onleesbaar gemaakt.

3. De constructie van een ingekapselde bron voldoet aan de eisen daaraan gesteld in de International Standard ISO 2919:1999 of recenter.

4. Indien, in tegenstelling tot hetgeen hierboven is voorgeschreven, de ingekapselde bron niet hoeft te voldoen aan de voorschriften in de International Standard ISO 2919:1999 of recenter of daaraan niet kan voldoen, dan is de constructie van de ingekapselde bron zodanig dat verspreiding van radioactiviteit wordt voorkomen.

5. De ingekapselde bron gaat vergezeld van een broncertificaat waarop de specifieke gegevens van de ingekapselde bron zijn weergegeven.

6. De omstandigheden waaronder het feitelijk gebruik van de ingekapselde bron plaatsvindt, mogen niet zwaarder zijn dan waarvoor deze is ontworpen.

7. Het beheer van de ingekapselde bron is zodanig dat steeds bekend is wat de gegevens van iedere bron zijn. De ingekapselde bron is daartoe, indien praktisch mogelijk, voorzien van een serienummer.

8. De ingekapselde bron is niet lek.

Handelingen

9. In de nabijheid van de ingekapselde bron zijn geen brandbare, brandbevorderende of explosieve stoffen aanwezig, tenzij hun aanwezigheid voor de bedrijfsvoering noodzakelijk is.

10. Een ingekapselde bron, toegepast in een vaste meetopstelling, wordt in de bergplaats opgeborgen indien:
    - dit uit het oogpunt van stralingshygiëne noodzakelijk is;
    - de meetopstelling definitief buiten gebruik is gesteld.

    Overige ingekapselde bronnen worden na gebruik opgeborgen in de bergplaats.

IV. Bergplaats

1. Het omgevingsdosisequivalenttempo aan de buitenzijde van de bergplaats is zo laag als redelijkerwijs mogelijk is. In ieder geval wordt op geen enkel punt op 0,1 meter afstand van het oppervlak van de bergplaats een omgevingsdosisequivalenttempo gemeten van meer dan 1 microsievert per uur.

2. De buitenzijde van de bergplaats is voorzien van een duidelijk leesbaar en onuitwisbaar opschrift "RADIOACTIEVE STOFFEN" en van een duidelijk zichtbaar waarschuwingsteken.

3. De bergplaats is deugdelijk afgesloten en kan uitsluitend geopend worden door de ondernemer en personen die daartoe van hem de bevoegdheid hebben gekregen.

4. De ondernemer zorgt ervoor dat de constructie van de bergplaats, al of niet deel uitmakend van een gebouw voldoet aan de eis dat de brandwerendheid niet lager is dan 60 minuten. Bij de bepaling van de brandwerendheid kan gebruik gemaakt worden van de in het Bouwbesluit genoemde toepasselijke NEN bladen.

5. De bergplaats is bekend bij de verantwoordelijke brandweer.

6. Wanneer de bergplaats eenvoudig te verplaatsen is, wordt deze geplaatst in een afsluitbare ruimte of kast, die deugdelijk is afgesloten en uitsluitend geopend kan worden door de ondernemer en personen die daartoe van hem de bevoegdheid hebben gekregen.

V. Overdracht radioactieve stoffen

1. Indien definitief geen handelingen meer met een ingekapselde bron zullen worden verricht, wordt daarvan binnen vier weken mededeling gedaan aan de Autoriteit Nucleaire Veiligheid en Stralingsbescherming, sector Stralingsbescherming, team Aanvragen en Melden. De ondernemer ontdoet zich van de ingekapselde bron, conform artikel 14a, onder b, van het Besluit stralingsbescherming. Na het zich ontdoen van de ingekapselde bron wordt dit aan de Autoriteit Nucleaire Veiligheid en Stralingsbescherming, sector Stralingsbescherming, team Aanvragen en Melden gemeld.

2. Radioactieve afvalstoffen worden zo spoedig als redelijkerwijs mogelijk is op adequate wijze afgegeven aan een aangewezen instelling of ophaaldienst zoals bedoeld in artikel 37, zevende en achtste lid, van het Besluit stralingsbescherming. Tijdelijke opslag van radioactieve afvalstoffen voor een

periode van maximaal twee jaar is toegestaan uit overwegingen die een efficiënte wijze van het zich ontdoen naar een erkende ophaaldienst beogen.

3. De radioactieve afvalstoffen, worden als zodanig herkenbaar op een deugdelijke wijze opgeslagen in een daarvoor bestemde ruimte die voldoet aan de eisen gesteld aan een bergplaats.

VI. Milieubelasting

1. De door de vergunde handelingen veroorzaakte bijdrage aan de effectieve dosis voor personen buiten de locatie is zo laag als redelijkerwijs mogelijk is. De MID overschrijdt in geen geval de waarde van 10 microsievert per jaar.

VII. Controle, registratie, meldingen en rapportages
A. Algemeen

1. Wijzigingen betreffende gegevens van de in hoofdstuk 1.III genoemde documenten worden vooraf gemeld aan de Autoriteit Nucleaire Veiligheid en Stralingsbescherming, sector Stralingsbescherming, team Aanvragen en Melden, Postbus 16001, 2500 BA Den Haag, onder vermelding van de vergunning waar de wijzigingen betrekking op hebben.

2. Het beheersysteem dat de administratie en de in de vergunning genoemde registraties en rapportages bevat zoals bedoeld in artikel 120 van het Besluit stralingsbescherming en de ministeriële regeling "Uitvoeringsregeling stralingsbescherming EZ" hoofdstuk 2 "Administratieve en organisatorische maatregelen stralingsbescherming" de artikelen 2.8 en 2.9, is tenminste vijf jaar op het kantoor van de toezichthoudend deskundige aanwezig.

3. De vergunning is fysiek of elektronisch beschikbaar op het kantoor van de toezichthoudend deskundige en op de plaats van de handelingen.

B. Radioactieve stoffen

1. Ingekapselde bronnen worden periodiek gecontroleerd.
   Minimaal jaarlijks vindt een visuele controle van de ingekapselde bron plaats. Wanneer deze wordt toegepast in een bronhouder vindt een visuele controle van de bronhouder plaats. Daarnaast wordt de ingekapselde bron en/of bronhouder/meetopstelling minimaal jaarlijks volgens een schriftelijk vastgelegde procedure gecontroleerd op lekken, radioactieve besmetting en op het omgevingsdosisequivalenttempo aan de buitenzijde van de bronhouder. Hierbij wordt beschadiging van de ingekapselde bron voorkomen.
   De resultaten van deze controles worden geregistreerd, onder vermelding van:
   - de datum van de controle,

- het nummer van de bron die is gecontroleerd,
- de wijze waarop de controle werd uitgevoerd,
- de naam van degene die de controle verrichtte, en
- de resultaten van de controle.

2. Wanneer de ingekapselde bron definitief niet meer wordt gebruikt, wordt aan deze ingekapselde bron, voordat deze wordt opgeslagen in de bergplaats of wordt overgedragen, volgens een schriftelijk vastgelegde procedure een lektest uitgevoerd.

3. In een speciaal daarvoor bestemd register, dat zich in of nabij de bergplaats bevindt, wordt de hoeveelheid radioactiviteit en/of die zich in de bergplaats bevindt, aangetekend. Deze registratie vindt minimaal plaats gespecificeerd naar nuclide en activiteit. Elke uitgifte of ontvangst van de ingekapselde bron uit of in de bergplaats wordt meteen in dit register aangetekend. Bij uitgifte wordt bovendien de bestemming aangetekend.

C. Rapportage

1. De in voorschrift II.2. van hoofdstuk 4 genoemde rapportage wordt voor 1 juni van ieder jaar over het voorgaande kalenderjaar uitgebracht. De rapportage bevat een opsomming van de activiteiten in dat kalenderjaar in het kader van de stralingsbescherming en van de resultaten daarvan. In deze opsomming komt in ieder geval een overzicht voor van:
   - alle aanwezige stralingsbronnen, gespecificeerd naar nuclide en activiteiten eventuele mutaties daarin, met vermelding van plaats en aard van de toepassing;
   - mutaties in de organisatie van de stralingsbescherming, zoals personele wijzigingen, gevolgde opleidingen, en dergelijke;
   - wijzigingen van de situatie binnen het kader van de vergunning; Zie ook voorschrift A.1.
   - de controlewerkzaamheden die zijn uitgevoerd en de resultaten daarvan;
   - calamiteiten en stralingsincidenten.

VIII. Stralingsincident, ongeval of radiologische noodsituatie

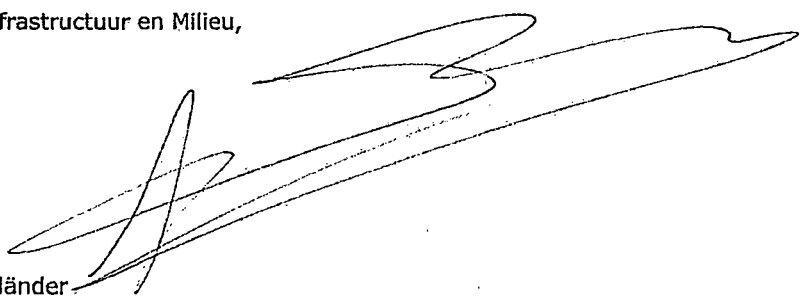
1. Bij een stralingsincident worden onverwijld zodanige maatregelen getroffen, dat (verdergaande) besmetting en/of blootstelling van personen wordt tegengegaan.

2. Een stralingsincident, ongeval of radiologische noodsituatie wordt terstond gemeld bij:
   het Meld- en informatiecentrum (088-4890000), dat 24 uur per dag bereikbaar is. Meldingen kunnen ook via de website worden gedaan: http://www.autoriteitnvs.nl/aanvragen-en-melden/melden-van-incident.

5. Ondertekening

Den Haag,

De Minister van Infrastructuur en Milieu,
namens deze:



drs. A.E.M. Niederländer
sectorhoofd directie Autoriteit Nucleaire Veiligheid en Stralingsbescherming

Belanghebbenden kunnen binnen 6 weken na de dag van verzending van dit besluit een bezwaarschrift indienen bij de directie Autoriteit Nucleaire Veiligheid en Stralingsbescherming, ter attentie van Hoofddirectie Bestuurlijke en Juridische Zaken van het Ministerie van Infrastructuur en Milieu, afdeling Algemeen Bestuurlijk-Juridische Zaken, Postbus 20901, 2500 EX Den Haag.
Dit besluit is verzonden op de in de aanhef van dit besluit genoemde datum.

Het bezwaarschrift moet van een handtekening, datum, naam en adres van de indiener zijn voorzien. De indiener dient duidelijk aan te geven waarom hij tegen dit besluit bezwaar aantekent.

Dit besluit treedt in werking met ingang van de dag na de dag waarop de termijn afloopt voor het indienen van een bezwaarschrift. Indien gedurende die termijn bij de voorzitter van de Afdeling bestuursrechtspraak van de Raad van State een verzoek om voorlopige voorziening is gedaan, treedt dit besluit niet in werking voordat op dat verzoek is beslist.

Voor nadere informatie over dit besluit kunt u terecht bij het Inspraakpunt Kernenergiewetvergunningen, telefoon 070 348 73 66, op werkdagen van 09.00 - 12.00 uur en van 14.00 - 17.00 uur. Ook is het mogelijk om uw vraag per e-mail te stellen aan Postbus.Aanvragenenmelden@anvs.nl onder vermelding van het kenmerk van dit besluit.

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