ISO-RAD™
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April 28, 2017

Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Ref: Submission of Quality Assurance Program for NRC approval for Temporary Louisiana License LA-13516-L01

Enclosed, please find a description of ISOFLEX Radioactive LLC's (ISO-RAD) Quality Assurance Program for your review and approval.

ISO-RAD is a user of Type A packages and Type B packages, and a distributor of sealed byproduct material in special form. We have no manufacturing capability and do not manufacture any product. Attachment 1 lists the sections of 10CFR Part 71 Subpart H which are applicable to our business. Attachment 2 is our company organization chart and Attachment 3 is a description of the ISO-RAD NRC Quality Assurance Program (QAP002).

Please direct any questions, comments or concerns to my attention. Phone: 504-305-4320, email: kjs@iso-rad.com or cell: 504-717-7811.

Sincerely,

Kevin J. Schehr, DBA
President & CEO
ISOFLEX Radioactive LLC

Attachment 1: Applicable sections of 10CFR Part 71 Subsection H
Attachment 2: ISO-RAD Organizational Chart
Attachment 3: ISO-RAD NRC QAP (QAP-002)

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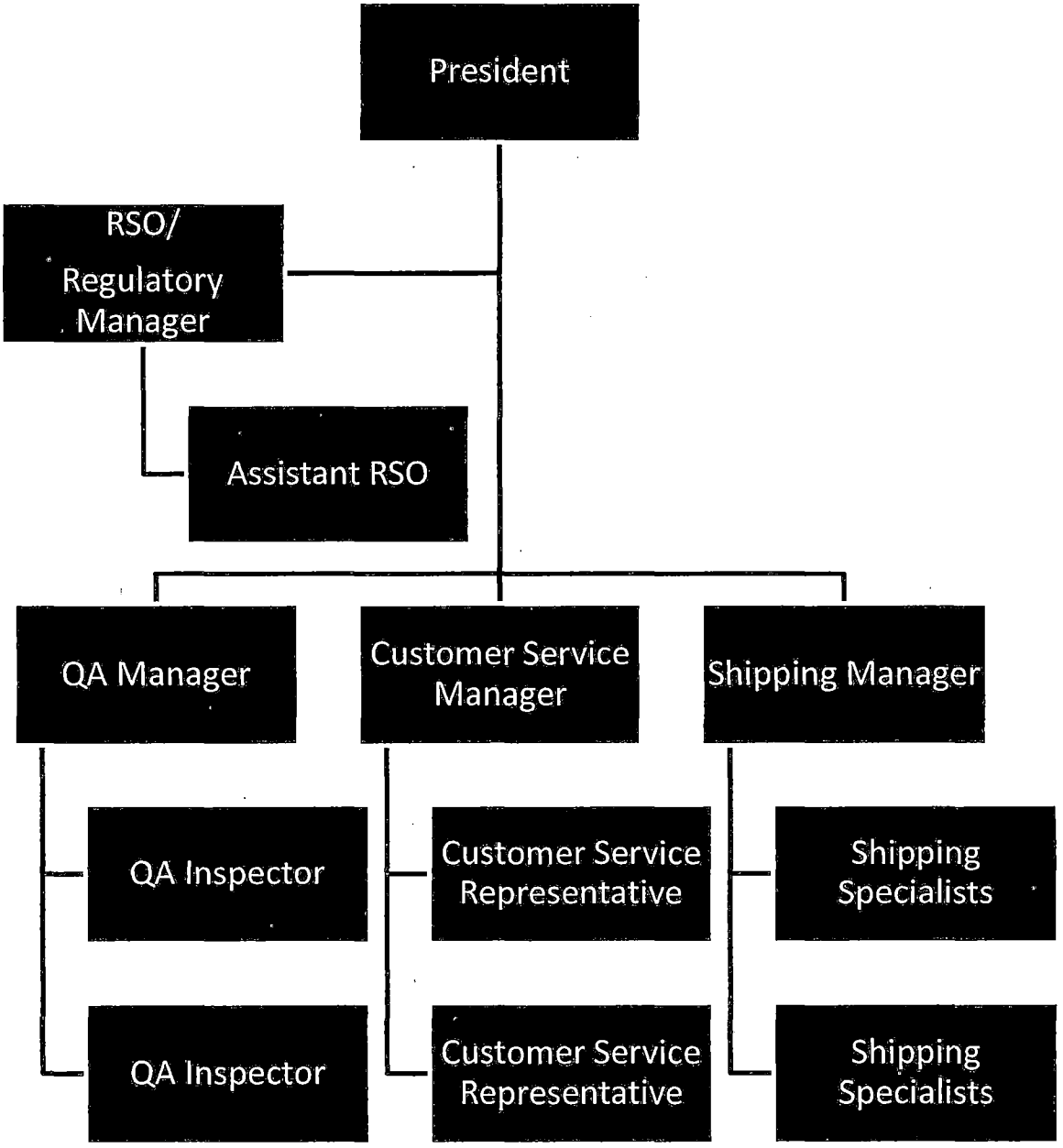
Q005
NMSS

Attachment 1 to ISO-RAD NRC QAP submission: Applicable sections of 10CFR Part 71, Subsection H

10 CFR Part 71 QAP Requirements	ISO-RAD QAP Section
71.101 Quality assurance requirements.	Attachment 1
71.103 Quality assurance organization.	2.1 - 2.4 (Organizational Chart)
71.105 Quality assurance program.	1.1 thru 1.5
71.106 Changes to quality assurance program.	1.6
71.107 Package design control.	N/A for ISO-RAD scope of work
71.109 Procurement document control.	5.1 and 5.2
71.111 Instructions, procedures, and drawings.	11.1 and 11.2
71.113 Document control.	3.1 thru 3.3
71.115 Control of purchased material, equipment, and services.	12.1 thru 12.3
71.117 Identification and control of materials, parts, and components.	13.1 and 13.2
71.119 Control of special processes.	N/A for ISO-RAD scope of work
71.121 Internal inspection.	15.1 thru 15.3
71.123 Test control.	N/A for ISO-RAD scope of work
71.125 Control of measuring and test equipment.	17.1 thru 17.3
71.127 Handling, storage, and shipping control.	18.1 thru 18.3
71.129 Inspection, test, and operating status.	19.1
71.131 Nonconforming materials, parts, or components.	6.1 thru 6.3
71.133 Corrective action.	7.1 thru 7.3
71.135 Quality assurance records.	8.1 thru 8.3
71.137 Audits.	10.1 thru 10.5

Attachment 2 to ISO-RAD NRC QAP submission: ISO-RAD Organizational Chart (ISO-RAD NRC QAP Approval)



Attachment 3 to ISO-RAD NRC QAP submission:
ISO-RAD's NRC QAP description (QAP-002)

REVISION	AUTHOR	CHECKED	APPROVED	DATE
0	Kevin J. Schehr	Richard H. McKannay	Kevin J. Schehr	01/02/2017

REVISION	PAGE NOS.	DETAILS	DATE
0	ALL	Original Document	01/02/2017

NOTE: THOSE ATTACHMENTS INDICATED IN THE TABLE OF CONTENTS AS FORMS MAY NOT BE INCLUDED IN PROCEDURE BUT ARE, RATHER, INCLUDED BY REFERENCE

REVISIONS TO THE TEXT OF THIS DOCUMENT ARE INDICATED IN THE MARGIN AS BELOW:

N | WHERE "N" INDICATES THE LATEST REVISION NUMBER

When Printed, this document becomes UNCONTROLLED

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1.0 USNRC Quality Assurance Program

1.1 The United States Nuclear Regulatory Commission (USNRC) requires an approved Quality Assurance Program (QAP) for all users of Type A and B packages. The use of a Type B package for this QAP is defined as the ordering, receipt, possession, repair, maintenance, preparation for transport, and offering for transportation of Type A or B packages. The use of a Type A or B package is controlled by ISOFLEX Radioactive LLC's (ISO-RAD)'s USNRC QAP and in ISO-RADs Operating and Emergency Procedures (O&E).

The Type A and B packages that ISO-RAD will use are radiography devices, source changers, storage containers, and transport containers. All activities important to transport package safety are implemented in accordance with this USNRC QAP, and suitable supporting documentation approved by appropriate levels of senior manager and managers.

1.1.1 This USNRC QAP, O&E, and supporting documentation contain appropriate requirements for accomplishing the activities ISO-RAD plans to conduct.

1.1.2 Evidence of conformance to these requirements is maintained as quality records that will be maintained in accordance with USNRC regulations.

1.2 ISO-RAD, through its USNRC QAP, provides control over activities affecting the safety and quality of the packages it will use. ISO-RAD will comply with the Type A and B manufacturers' maintenance and Type B certificate requirements.

1.3 ISO-RAD's QAP requirements and O&E procedures are based upon the following considerations concerning the complexity and proposed use of the package and its components.

1.3.1 The results of functional checks, inspections, and tests will demonstrate compliance with requirements and procedures.

1.3.2 ISO-RAD will maintain an inspection history and determine and record noncomformances found during inspection, maintenance and repair functions.

1.4 The status and adequacy of the USNRC QAP are reviewed at established intervals and will be conducted and recorded in accordance with procedures.

1.5 Managers of all departments participating in the USNRC QAP regularly review the status and adequacy of the corresponding part of the USNRC QAP the manager is responsible.

1.6 Changes to ISO-RAD's QAP require approval from the NRC in accordance with 10CFR Part 71.106(a).

1.6.1 Changes that <u>do not</u> reduce the commitments in the quality assurance program may be changed without approval from the NRC in accordance with 10 CFR Part 71.106(b). Those changes must, however, be submitted to the NRC every 24 months IAW 71.1(a).

1.6.2 Changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or

editorial items, are examples of changes that do not reduce commitments in the quality assurance program as mentioned in section 1.6.1.

2.0 Organization

2.1 ISO-RAD is the responsible party for the creation and implementation of the USNRC QAP. The Quality Assurance Manager (QAM) is directly responsible for the execution, maintenance, and continuous improvement of the USNRC QAP system. ISO-RAD can delegate parts of the USNRC QAP, but maintains ultimate responsibility for compliance of the USNRC QAP.

2.2 The QAM has duties and is given authority to operate autonomous of Senior Management. The QAM may delegate authority and duties to other managers in the execution of their duties in their respective departments. Managers and individual members of the organization have the authority and duty under the USNRC QAP to perform activities affecting safety functions finished goods, parts and components. These duties include functions necessary to attain quality objectives as stated in the USNRC QAP and procedures.

2.3 Quality Assurance Manager Responsibilities

2.3.1 Establish and implement an effective and compliant USNRC QAP.

2.3.2 The QAM is responsible for creating and maintaining the corrective/ preventative action system.

2.3.3 Ensure and verify that important to safety items and processes as stated in 1.2 are performed in accordance with regulations and procedures.

2.3.4 QAM reports to the president of ISO-RAD without interference from other senior managers or managers. This ensures complete authority and autonomous freedom to conduct USNRC QAP activities without fear of retribution. The QA department must have the appropriate funding to have the proper equipment and personnel to conduct USNRC QAP operations.

2.3.5 The QAM and the QA personnel performing USNRC QAP functions have the level of authority and organizational freedom appropriate to identify and correct non- conformances without retribution from senior manager, managers, or other employees.

2.3.6 Any employee or company department that is assigned USNRC QAP functions have the required responsibility, authority, and organizational freedom to ensure implementation of the USNRC QAP or any portion of the USNRC QAP. Any person performing QA functions within the organization have direct access to the QAM and the president as necessary to perform their duties.

2.4 ISO-RAD has an official organizational chart that demonstrates the primary job functions and the reporting authority of the job functions.

3.0 Document Control

3.1 ISO-RAD's USNRC QAP covers all work instructions, procedures, and drawings. The revisions or changes to these documents are controlled and maintained in accordance with the USNRC QAP and the specific procedures created to describe document control.

3.2 The document control procedures ensure that controlled documents are reviewed and approved for release by authorized personnel. The QAM controls the distribution and where the activity is performed.

3.2.1 The QAM maintains a master document list and is responsible for distribution of documents in the list as stated in the document control procedures. The QAM will mark obsolete or superseded controlled documents on the master list.

3.2.2 The QAM and department managers are responsible for reviewing documents periodically for corrections, relevance, and compliance with regulations. These reviews ensure that controlled documents meet internal and external regulations.

3.2.3 Work instructions and procedures describing tests or inspections will have a stopping point to allow for the test or inspection to occur. The stopping point must be tested before initial implementation and upon each revision and approved by the QAM.

3.3 The document control procedures ensure that document revisions and changes are reviewed and approved by authorized persons.

4.0 Design Control

4.1 Not applicable for the scope of work at ISO-RAD.

5.0 Procurement Control

5.1 ISO-RAD's USNRC QAP uses documented procedures, work instructions, and drawings to ensure compliance when procuring Type A and B packages, accessories, replacement parts, components, other equipment, and services. The QAP also ensures that the same methods are applied to contractors and subcontractors used by ISO-RAD.

5.1.1 ISO-RAD procurement documents must clearly describe the item to be purchased so that both ISO-RAD and the vendor understand the item to be purchased.

5.1.2 The description has the following elements when necessary; a certificate from the vendor of a Type A or B package stating that a particular serial number package conforms to the USNRC or USDOT Certificate of Compliance.

5.1.3 The procurement document must include approval signatures of a senior manager.

5.1.4 All nonconforming Type A or B packages, finished goods, parts, and components will be tagged, separated and controlled by the QAM or designee as stated in the appropriate procedures.

5.1.5 ISO-RAD procurement documents are official Quality Assurance Records as stated in Section 8.0. ISO-RAD will maintain these records in accordance with procedures and USNRC guidelines.

5.2 ISO-RAD requires contractors and subcontractors to also have a QAP that is equal to ISO-RAD's program.

5.2.1 For vendors, contractors, and subcontractors of special services or processes, calibration of equipment, and important to safety items. The QAM will evaluate the vendors, contractor, or subcontractors QAP and thereafter periodically review their QAP in accordance with ISO-RAD procedures.

5.2.2 The QAM will make vendors, contractors, and subcontractors aware of the USNRC requirement for compliance with 10 CFR Part 21, USNRC deliberate misconduct policy, and any certification or calibration requirements to ensure the conformance of supplied items.

6.0 Non-Conforming Materials, Parts, or Components

6.1 ISO-RAD uses documented procedures, work instructions, and drawings to ensure that finished goods, parts, components, equipment and services that do not conform are segregated and controlled by the QAM or designee to prevent inadvertent use.

6.1.1 The nonconforming part procedures will include methods to identify, segregate, disposition, notify internal personnel, and notify external vendors of nonconforming parts.

6.2 ISO-RAD will return all nonconforming parts to the vendor with a written report of the nature of the nonconformance.

6.3 The maintenance of nonconforming parts in as stated in Section 8.0 Quality Assurance Records.

7.0 Corrective Action

7.1 Adverse conditions to quality include defective material, deficiencies, nonconformances, deviations, defective equipment, and methods are in place to quickly identify and correct the above, which is documented in written procedures.

7.1.1 ISO-RAD will take the appropriate action in the corrective/preventative process to ensure that the cause of the condition is determined, corrective action is taken, and the process is documented according to procedures.

7.2 A significant to quality or safety nonconformance requires a documented investigation to determine the cause of the condition and corrective action be implemented to prevent another occurrence.

7.2.1 Identifying a condition that is averse to safety or significant to quality is immediately reported to the QAM and/or a senior manager.

7.2.2 The corrective action report is maintained as a quality record in accordance with Section 8.0.

7.3 The QAM is responsible for creating and maintaining the corrective/preventative action system.

8.0 Quality Assurance Records

8.1 ISO-RAD's document retention program is based on the USNRC's recommended retention of documents. The retained documents are legible, retrievable, maintained, and readily available and include records that are sufficient to describe and provide evidence of activities affecting the quality of Type A or B packages.

8.1.1 The Quality Assurance Records include all documents related to the USNRC QAP and all supporting documents such as work instructions, procedures, drawings, procurement documents, personnel training records, and equipment documentation.

8.2 Detailed work instructions and procedures describe the creation, periodic review, transfer, distribution list, storage and retention, and responsible party for all Quality Assurance Records.

8.3 Quality Assurance Records are maintained and retained in accordance with ISO-RAD procedures and the USNRC's regulatory guidance.

8.3.1 ISO-RAD will retain Quality Assurance Records for a period of three (3) years beyond the date of last activity in the area covered by the records.

8.3.2 In the case of superseded Quality Assurance Records, ISO-RAD will maintain the superseded documents for a period of three (3) years.

9.0 Staff and Training

9.1 All ISO-RAD employees are indoctrinated, trained, and qualified as necessary in USNRC QAP responsibilities.

9.2 Employees performing USNRC QAP activities are provided indoctrination and training as necessary to carry out quality and safety duties. Additional training will be given as necessary.

9.3 Training records are part of the Quality Assurance Records and will be maintained in accordance with Section 8.0 of the USNRC QAP.

10.0 Audits

10.1 The USNRC QAP provides for documented procedures and work instructions describing the ISO-RAD audit system. The system includes periodic and planned audits by qualified personnel to determine if the USNRC QAP promotes an atmosphere of continuous improvement and is effective.

10.1.1 As a minimum, a USNRC QAP audit is required annually.

10.1.2 The QAM and/or senior managers will conduct unscheduled audits as deemed appropriate to ensure compliance with the USNRC QAP.

10.2 ISO-RAD audits are conducted with the USNRC QAP, work instructions, and procedures. An audit checklist may be used in lieu of formal instructions if the person performing the audit is not normally responsible for the area being audited.

10.2.1 To make audits unbiased, the audits shall be conducted by qualified personnel without organization responsibility for the area being audited.

10.2.2 Auditors are trained and qualified to conduct audits on behalf of the QAM.

10.2.3 All audit results are formally documented including recommended actions. The findings and recommendations are reviewed; corrective actions are taken and incorporated into the Quality Assurance Records according to USNRC QAP Section 8.0.

10.3 Findings during an audit are subject to corrective action. The corrective action will comply with USNRC QAP Section 7.0.

10.4 A formal review of Audit Reports by senior managers and managers responsible for the area audited is required.

10.5 Audit findings and corrective actions taken are re-audited during the next audit.

11.0 Work Instructions, Procedures, and Drawings

11.1 All activities that affect the USNRC QAP or quality of products are described in the work instructions, procedures, and drawings to ensure compliance with the USNRC QAP and regulatory requirements.

11.1.1 The USNRC QAP documents describe the method(s) to accomplish compliance with appropriate regulations, USNRC QAP requirements, Certificate of Compliance conditions, and RAM license conditions.

11.1.2 The creation and use of the USNRC QAP documents is mandatory.

11.1.3 The documents are controlled in accordance with USNRC QAP Section 3.0.

11.2 The work instructions, procedures, and drawings will include qualitative and quantitative accept/reject criteria that will clearly demonstrate if a Type A or B package, finished good, part, or component is acceptable for use.

12.0 Control of Purchased Equipment, Materials, and Services

12.1 ISO-RAD will purchase Type A or B packages, finished goods, parts, components, equipment, and services that will be controlled according to work instructions, procedures, and drawings ensuring conformance to procurement documents.

12.1.1 USNRC QAP Section 15.0 describes internal inspection of Type A or B packages, finished goods, parts, components, and equipment. This section is used when conformance to procurement documents can be ensured through inspection upon delivery to ISO-RAD.

12.1.2 In the case when conformance to procurement documents cannot be ensured by ISO-RAD internal inspection, then ISO-RAD will rely upon the contractor,

subcontractor, or vendor furnishing quality evidence of compliance to procurement documents.

12.1.2.1 Contractors, subcontractors, and vendors are evaluated using work instructions and procedures to objectively evaluate the reviewee's ability to comply with the requirements of ISO-RAD's USNRC QAP, regulatory requirements, and purchasing requirements. The level of qualification is tied to the level of importance to safety of the item being procured.

12.1.2.2 The contractor, subcontractor, or vendor may be required to provide objective evidence of quality by supplying test samples, certification of conformance, and QA inspection reports.

12.1.2.3 ISO-RAD will have to determine the effectiveness of contractors, subcontractors, and vendors control quality within their respective organization the level of scrutiny is determined by the level of important to safety the item being purchased.

12.2 ISO-RAD will maintain Quality Assurance Records as evidence that Type A and B packages, finished goods, parts, components, and equipment conforms to the procurement specifications.

13.0 Identification and Control of Purchased Equipment, Materials, and Services

13.1 ISO-RAD has a documented identification system designed to stop the use of uninspected, nonconforming, defective, or incorrect finished goods, parts, components, and equipment.

13.1.1 The documentation describes the physical identification using marking, tagging, and stamping to maintain control and traceability before, during, and after distribution.

13.2 The work instruction and procedures describe the system and method for which Type A and B packages, finished goods, parts, and components are serialized and lot controlled before, during, and after distribution.

14.0 Control of Special Processes

14.1 Not applicable for the scope of work at ISO-RAD.

15.0 Internal Inspection

15.1 Internal inspection is the primary method of determining if Type A or B packages, finished goods, parts, components, and equipment conform to the procurement/ purchasing documents. The internal inspections are conducted by qualified personnel using work instructions, procedures, and drawings. Internal inspections also may take the form of receiving, in-process, and final inspections of parts.

15.1.1 Personnel performing inspections are required to be trained and qualified in the method of inspection used.

15.1.2 The person making the part cannot perform the quality inspection.

15.1.3 Inspection results are recorded according to the work instructions and procedures and maintained according to USNRC QAP Section 8.0.

15.1.4 Inspection personnel training and qualification records are maintained according to USNRC QAP Section 8.0.

15.2 If a physical inspection of a Type A or B package, finished good, part, and component cannot be accomplished, indirect control is used by monitoring the process methods, equipment, and personnel.

15.3 A combination of methods is required when either inspection or monitoring are inadequate.

16.0 Test Control

16.1 Not applicable for the scope of work at ISO-RAD

17.0 Control of Measuring and Test Equipment

17.1 ISO-RAD will maintain documented work instructions, procedures, and drawings to ensure that gauges, instruments, tools, measuring devices, and other testing devices used in quality activities are controlled, calibrated, set or adjusted to the proper settings to maintain the accuracy of the result.

17.1.1 Calibrations can be performed in house if practical. ISO-Rad shall have traceable standards. If a calibration method does not exist, the basis for calibration is documented and retained in the Quality Assurance Records.

17.1.2 Calibration records must be traceable to the item being calibrated.

17.1.3 The calibration sticker will indicate the date of calibration and the date the next calibration is due.

17.2 When uncalibrated or out of calibration equipment is found, steps are immediately taken to validate previous inspection results.

17.3 Equipment that is found to be out of tolerance on a consistent basis, the equipment must be taken out of service and replaced, or repaired.

18.0 Handling, Storage, and Shipping Control

18.1 The methods for handling, storage, shipping, cleaning and preservation of finished goods, parts, components, and equipment that will be used in Type A or B packages must be documented in work instructions and procedures. The purpose is to prevent damage and deterioration.

18.2 Radiography and transport packages are durable and stable and do not require special handling or storage to prevent deterioration for environmental effects.

18.3 Type A and Type B packages shipped and received according to documented work instructions and procedures to ensure compliance with USNRC QAP, USNRC regulations, USDOT regulations, and other regulatory bodies.

19.0 Inspection, Test, and Operating Status

19.1 USNRC QAP compliance requires documented work instructions, procedures, and drawings that indicate the status of inspections and tests performed on Type A and B packages, finished goods, parts, and components.

19.1.1 ISO-RAD's status indicators include labels, color codes, tags, or other devised means as described in work instructions and procedures.

19.1.2 ISO-RAD's status indicators clearly differentiate between acceptable and unacceptable on finished goods, parts, and components with the purpose of preventing the inadvertent use of unacceptable items as described in work instructions and procedures.