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SUBJECT: LICENSE EXEMPTION FOR GAMMA RADIOGRAPHY SURVEY
INSTRUMENT CALIBRATION PERIODICITY

Title 10 Code of Federal Regulations Part 30.11(a) states that the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulation in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Title 10 Code of Federal Regulations Part 34.25 requires the following for gamma radiography programs:

“(a) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make the radiation surveys required by this part and by 10 CFR part 20 of this chapter. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (1 rem) per hour.

(b) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated--

(1) At intervals not to exceed 6 months and after instrument servicing, except for battery changes;

(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with § 34.65.”

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The Department of the Navy (DON) has engaged in a rigorous program over the previous decade to measure and document the effectiveness of its radiation survey instruments in maintaining their calibration accuracy through “as-found” measurements when the instruments are received for periodic calibration. The overwhelming data for the gamma radiography survey instruments (IM-231()/PD series ion chambers) demonstrate that the instruments would maintain calibration accuracy within the calibration tolerances required per 10 Code of Federal Regulations Parts 34.25(b)(2) and (3) for greater than twelve months. As such, the DON requests an exemption such that gamma radiography survey instruments may be calibrated at intervals not to exceed twelve months vice six months. Continuing the current calibration interval of six months unnecessarily expends DON radiation survey instrument calibration resources and increases potential radiation exposure to calibration technicians with no appreciable benefit to instrument performance or reliability. The exemption would not put an undue risk on public health and safety, and is in the best interest of national security. Enclosure (1) provides justification for the license exemption for survey instrument calibration.

Gamma radiography operations conducted by the Navy are safer than that of the commercial industry. According to the IAEA, the majority of accidents happen because radiographers become complacent. The IAEA further states: “These accidents are mostly caused by overconfidence and by shortcuts that are driven by a desire to reduce costs. Industrial radiography is a competitive business and reducing cost is a matter of survival for some companies. Often radiographers are paid for the number of radiographs taken. Other circumstances add to the problem: radiographs are often taken in difficult locations (sometimes during the night or with low light) and radiographers often work alone without direct supervision.” The Navy’s additional safety precautions not usually observed or taken in the commercial industry are mentioned below.

a. The Navy has a level of oversight and management involvement (Senior Radiographers and Radiation Safety Officers on the job) that is rarely observed in civilian industry. Specific items include the following: required frequent supervisory surveillances and management involvement, annual drills that involve security and safety departments, and a self-reporting culture that facilitates process improvements. If a condition is found during radiography operations that does not meet standards (it may even include an askew sign), the operation is stopped and critiqued. Gamma radiography work will not re-start until corrective actions have been taken. Subsequently, these corrective actions are benchmarked and disseminated to other gamma radiography commands within the Navy.

b. There is a high emphasis on radiography equipment and exposure device inspections and maintenance, which includes checklists and written procedures. Multiple signatures are required to verify inspections, to include the signatures of radiographers and other supervisory personnel.

c. Training provided to radiography personnel exceeds the minimum requirements of 10 CFR 34.43. The Navy also holds annual conferences with radiographers and RSOs where lessons learned are shared and refresher training is conducted. The RSOs are required to accumulate 5 continuing education units every five years, otherwise their qualifications will expire and they will have to attend RSO training to re-qualify.

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d. The work environment on Navy vessels and facilities is extremely clean compared to the environments usually encountered at pipelines, oil platforms, and other true field-work locations. This cleaner environment results in a lower likelihood of equipment damage and malfunction. The illumination on-board Navy vessels is excellent; thus, diminishes the possibility of an accident.

e. Radiography commands only use survey instruments and dosimetric devices with a lengthy track record of stability. These instruments and devices are also maintained by rigorous programs for maintenance, processing, and calibration. Those items that do not meet these expectations are replaced by either new instruments or technology.

f. Radiography personnel are required to wear a TLD and an EPD at all times regardless of whether they are working in a permanent radiography installation (PRI) equipped with other alarming and warning devices or working within close proximity to a loaded exposure device.

g. Radiographers work to a control level set at one tenth of the federal limit. That control level can only be exceeded with prior written approval from the Commanding Officer. Additionally, Navy EPDs are set to alarm at 200 mrem/hr vice the 500 mrem/hr required in 10 CFR 34.47.

h. Two radiographers are always required for conducting operations other than in a PRI. A secondary radiographer must always be close to the primary radiographer who is operating the camera, in case help is needed. During these operations a Radiographer In-Charge (RIC) is responsible for ensuring all safety aspects of a temporary job site (TJS) are met prior to and after each exposure, including a dosimetry check. These TJS evolutions are well planned. The planning phase encompasses various meetings to evaluate all radiography safety issues. Whenever possible, lead shielding is used in a radiography area to reduce the exposures and minimize the restricted area. Emergency radiography does not occur in the Navy, and there are no unknown sites and unknown conditions.

i. Barrier monitors are utilized as an additional protective measure to secure access to the restricted area. The barrier monitors wear the same dosimetry and EPDs as the radiographers and are trained to operate RADIAC instrumentation. The barrier monitors ensure that only personnel authorized by the radiographer are able to enter the restricted area. If conditions change or unexpected levels of radiation are measured at the barrier, the monitors immediately contact the radiographer in charge.

The above attributes and close attention to detail make radiographic operations within the Navy one of the safest in the country. In closing, the exemption request is based upon the Navy's unique program management oversight, training, equipment, procedures, and safety culture.

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If you have additional questions, please do not hesitate to contact me via telephone at (703) 695-2020 or through electronic mail at anthony.s.williams4@navy.mil.

Sincerely,

A. S. WILLIAMS
Captain, Medical Services Corps,
United States Navy
Executive Secretary
National Radiation Safety Committee

Enclosures: 1. Justification for License Exemption of Survey Instrument Calibration Periodicity

Copy to: Naval Sea Systems Command (SEA 04N, SEA 04ND)
Naval Sea Systems Command Detachment, Radiological Affairs Support Office

JUSTIFICATION FOR LICENSE EXEMPTION OF SURVEY INSTRUMENT CALIBRATION PERIODICITY

Reference (a): ANSI N323AB – 2013, American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments

1. Background.

The Department of the Navy (DON) has an established process for monitoring and adjusting the calibration intervals for its radiation survey instruments. The intent is to establish and maintain an appropriate calibration interval for each instrument type such that greater than 85% of the instruments maintain calibration throughout the entire calibration interval. This leads to greater efficiency, cost minimization, as well as a reduction in calibration technician radiation exposure. The gamma radiography survey instrument calibration interval maximum of six months appears to be overly conservative based on the DON's calibration interval monitoring which indicates that a calibration interval of greater than 12 months would be acceptable per reference (a). The DON is requesting that the calibration interval maximum of six months for gamma radiography survey instruments be modified to allow use of calibration intervals up to 12 months based on and informed by execution of a reference (a) compliant calibration interval monitoring process.

2. Description of DON Calibration Interval Monitoring Methodology and Process

a. Reference (a), Paragraph 3.5, provides requirements for calibration frequency and specifies that calibration frequency shall not exceed one year, but provides methodologies for adjustment after the calibration routine is established. Under this process, if greater than 10% of the as-found responses of the instruments are out of the calibration acceptance range, consideration should be given to increasing the calibration frequency. Reference (a) also provides guidance for extending the calibration frequency beyond one year based on instrument reliability. It lists five acceptable methods to evaluate calibration frequency in order to make changes. The DON Radiation Detection, Indication and Computation (RADIAC) Program uses Method 5, a statistical analysis of instrument types based on as-found readings recorded during calibration.

b. As part of Standard Calibration Procedures, DON RADIAC Calibration Laboratories take as-found readings during condition received checks before any adjustments are made. Results of the as-found readings are recorded and used in the calibration interval analysis.

c. Each calendar quarter, the as-found readings for each survey instrument type are collated for analysis. The data and calculations include the following:

(1) Long Running Failure Rate (Fail %) and Long Running Actual Reliability (R_{actual}). The current data set includes data from 2006 until present. Where a change in calibration frequency or a technical change in the calibration procedure has occurred that affects the data (change in calibration point, for example), the data is evaluated from the date of the change.

(2) Current Calibration Interval (I).

Enclosure (1)

JUSTIFICATION FOR LICENSE EXEMPTION OF SURVEY INSTRUMENT CALIBRATION PERIODICITY

(3) Recommended Calibration Intervals (I_{new}) to achieve a Target Reliability (R_{target}) of 0.90 (desired) and 0.85 (action level).

(4) % Fail for the current quarter.

(5) A graphical representation of R_{actual} as compared to R_{target} of 0.90 over the past 12 months.

(6) Estimated changes in I_{new} to achieve R_{target} of 0.85 and 0.90 if historically poorly performing instruments are removed from service, and the subsequent calculations.

d. This data is reviewed by the equipment lead engineers who conduct an analysis of the calibration intervals. A report is developed to document this analysis and any related recommendations. The nominal R_{actual} action level range for recommending calibration interval changes is 0.85 – 0.95.

e. The report is reviewed by the RADIAC Program Office (including the RADIAC Technical Warrant Holder) and decisions documented for any recommendations.

f. Following calibration interval adjustment, the as-found data is reset so that the prior data does not mask the anticipated changes. The new data is monitored to ensure that any unexpected instrument reliability trends are identified and promptly addressed.

g. Calibration interval analysis information is also included in biannual equipment life cycle audits and is based on the most recent calibration interval analysis preceding the life cycle audit.

h. This methodology is supported by stringent response check policies for in-service instruments per reference (a). All DON radiography commands are issued appropriate response check radioactive sources and are required to ensure that gamma radiography survey meters are responding properly to a known quantity of radioactivity prior to use.

3. Results of DON Calibration Interval Monitoring for IM-231()/PD Survey Meters

a. Data from calibration interval monitoring for IM-231()/PD instruments with a six month calibration interval (used in gamma radiography applications) as conducted over the past nine years is indicated below. The observed % Fail rate of 2.2 % (and the corresponding R_{actual} of 0.978) has been slowly improving over this period (from ~5 % in 2012 to 2.2 % in 2020) as newer model instruments have been placed in service. The statistical analysis indicates that a calibration interval of greater than 12 months would be acceptable per reference (a), as indicated by the calculated new intervals (I_{new}) of 13 months (R_{target} 0.90) and 20 months (R_{target} 0.85), depending on the desired target reliability.

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RADIAC	Cal Interval (I)	Total # Instruments Monitored	# Pass	# Fail	% Fail	I_{new} (R_{target} 0.90)	I_{new} (R_{target} 0.85)
IM-231()/PD	6 months	5515	5391	124	2.2	13 months	20 months

b. A small number of IM-231()/PD instruments are used in DON non-gamma radiography applications where the calibration interval is 12 months. Data from calibration interval monitoring for these instruments is indicated below. Although the data set is much smaller, it does indicate that these instruments perform as good as or better than predicted by the six month calibration interval data calculations, with R_{actual} of 0.951 for the monitored instruments after 12 months in service.

RADIAC	Cal Interval (I)	Total # Instruments Monitored	# Pass	# Fail	% Fail	I_{new} (R_{target} 0.90)	I_{new} (R_{target} 0.85)
IM-231()/PD	12 months	103	98	5	4.9	22 months	35 months

4. Summary

The current American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments (reference (a)) provides guidance for determining appropriate calibration intervals for radiation survey instruments. The DON is currently following that protocol, and has determined that the ion chamber survey meters used in the conduct of DON gamma radiography operations consistently perform well enough to support a calibration interval of up to 12 months. Continuing the current calibration interval of six months unnecessarily expends DON RADIAC calibration resources and increases potential radiation exposure to RADIAC calibration technicians with no appreciable benefit to RADIAC performance or reliability. The requested exemption, when combined with DON's stringent RADIAC response check policies during instrument use, would not put an undue risk on public health and safety, and is in the best interest of national security.