

OHIO DEPARTMENT OF HEALTH

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BOB TAFT
Governor

J. NICK BAIRD, M.D.
Director of Health

August 9, 2001

Fred Combs
United States Nuclear Regulatory Commission
Assistant Director
Office of State and Tribal Programs
Washington, D.C. 20555

Dear Mr. Combs,

Please find enclosed Ohio rule 3701:1-46, "General Licenses and Licenses for Manufacturing and Distribution". This is Ohio's version of 10 CFR 31 and 10 CFR 32. The rule is being sent to you for USNRC review.

Please feel free to contact Marcia Howard or myself at 614-644-2727 if there are any questions.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Snee".

Michael J. Snee
Ohio Department of Health
Bureau of Radiation Protection

cc: James L. Lynch, State Agreements Officer

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General Licenses and Licenses for Manufacturing and Distribution

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3701:1-46-01 DEFINITIONS.

TERMS DEFINED IN RULES 3701:1-38-01 AND 3701:1-40-01 OF THE ADMINISTRATIVE CODE SHALL HAVE THE SAME MEANING WHEN USED IN THIS CHAPTER EXCEPT TERMS REDEFINED WITHIN A GIVEN RULE FOR USE WITHIN THAT RULE ONLY. AND ADDITIONALLY, AS USED IN THIS CHAPTER:

(A) LOT TOLERANCE PERCENT DEFECTIVE MEANS, EXPRESSED IN PERCENT DEFECTIVE, THE POOREST QUALITY IN AN INDIVIDUAL INSPECTION LOT THAT SHOULD BE ACCEPTED.

Effective date:

R.C. 119.032 review date:

Certified by:

Jodi Govern, Secretary
Public Health Council

Date

Rule promulgated under: Chapter 119

Rule authorized by: section 3748.02

Rule amplifies: section 3748.02

Prior effective date: none

3701:1-46-02 PURPOSE AND SCOPE.

- (A) THIS CHAPTER ESTABLISHES GENERAL LICENSES FOR THE POSSESSION AND USE OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM AND A GENERAL LICENSE FOR OWNERSHIP OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM. SPECIFIC PROVISIONS OF CHAPTER 3701:1-40 OF THE ADMINISTRATIVE CODE ARE APPLICABLE TO GENERAL LICENSES ESTABLISHED BY THIS PART. THESE PROVISIONS ARE SPECIFIED IN RULE 3701:1-46-03 OF THE ADMINISTRATIVE CODE OR IN THE PARTICULAR GENERAL LICENSE.
- (B) THIS CHAPTER PRESCRIBES REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES TO PERSONS WHO MANUFACTURE OR INITIALLY TRANSFER ITEMS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM FOR SALE OR DISTRIBUTION TO PERSONS GENERALLY LICENSED UNDER CHAPTERS 3701:1-46 OF THE ADMINISTRATIVE CODE OR 10 C.F.R. 35 OR EQUIVALENT AGREEMENT STATE OR NARM LICENSING STATE REGULATIONS.
- (C) THIS CHAPTER ALSO PRESCRIBES CERTAIN RULES GOVERNING HOLDERS OF THESE LICENSES. IN ADDITION, THIS CHAPTER PRESCRIBES REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES TO PERSONS WHO INTRODUCE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM INTO A PRODUCT OR MATERIAL OWNED BY OR IN THE POSSESSION OF THE LICENSEE OR PERSON AND RULES GOVERNING HOLDERS OF SUCH LICENSES. FURTHER, THIS CHAPTER DESCRIBES PROCEDURES AND PRESCRIBES REQUIREMENTS FOR THE ISSUANCE OF SEALED SOURCE & DEVICE CERTIFICATES (COVERING RADIATION SAFETY INFORMATION ABOUT A PRODUCT) TO MANUFACTURERS OR INITIAL TRANSFERORS OF SEALED SOURCES OR DEVICES CONTAINING SEALED SOURCES WHICH ARE TO BE USED BY PERSONS SPECIFICALLY LICENSED UNDER CHAPTER 3701:1-40 OF THE ADMINISTRATIVE CODE OR EQUIVALENT REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR FOR NARM, A NARM LICENSING STATE.
- (C) THE PROVISIONS AND REQUIREMENTS OF THIS CHAPTER ARE IN ADDITION TO, AND NOT IN SUBSTITUTION FOR, OTHER REQUIREMENTS OF CHAPTER 3701:1-40 OF THE ADMINISTRATIVE CODE WHICH APPLY TO APPLICATIONS AND LICENSES SUBJECT TO THIS CHAPTER.

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Jodi Govern, Secretary
Public Health Council

Date

Rule promulgated under: Chapter 119

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Rule amplifies: section 3748.02

Prior effective date: none

3701:1-46-03 TERMS AND CONDITIONS.

- (A) THE GENERAL LICENSES PROVIDED IN THIS CHAPTER ARE SUBJECT TO THE PROVISIONS OF RULES 3701:1-38-09, PARAGRAPH (D) OF 3701:1-40-08, PARAGRAPHS (A) TO (C) OF 3401:1-40-16, 3701:1-40-19, 3701:1-40-20, 3701:1-40-21, AND 3701:1-38-06 OF THE ADMINISTRATIVE CODE AND CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE UNLESS INDICATED OTHERWISE IN THE SPECIFIC PROVISION OF THE GENERAL LICENSE. ATTENTION IS DIRECTED PARTICULARLY TO THE PROVISIONS OF THE REGULATIONS IN CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE WHICH RELATE TO THE LABELING OF CONTAINERS.

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Rule amplifies: section 3748.02
Prior effective date: none

3701:1-46-04 CERTAIN DEVICES AND EQUIPMENT.

A GENERAL LICENSE IS HEREBY ISSUED TO TRANSFER, RECEIVE, ACQUIRE, OWN, POSSESS AND USE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM INCORPORATED IN THE FOLLOWING DEVICES OR EQUIPMENT WHICH HAVE BEEN MANUFACTURED, TESTED AND LABELED BY THE MANUFACTURER IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN A SPECIFIC LICENSE ISSUED TO HIM BY THE DEPARTMENT.

- (A) STATIC ELIMINATION DEVICE. DEVICES DESIGNED FOR USE AS STATIC ELIMINATORS WHICH CONTAIN, AS A SEALED SOURCE OR SOURCES, BYPRODUCT MATERIAL CONSISTING OF A TOTAL OF NOT MORE THAN 18.5 MEGABECQUERELS (FIVE HUNDRED MICROCURIES) OF POLONIUM-210 PER DEVICE.

- (B) ION GENERATING TUBE. DEVICES DESIGNED FOR IONIZATION OF AIR WHICH CONTAIN, AS A SEALED SOURCE OR SOURCES, BYPRODUCT MATERIAL CONSISTING OF A TOTAL OF NOT MORE THAN 18.5 MEGABECQUERELS (FIVE HUNDRED MICROCURIES) OF POLONIUM- 210 PER DEVICE OR OF A TOTAL OF NOT MORE THAN 1.85 GIGABECQUERELS (FIFTY MILLICURIES) OF HYDROGEN -3 (TRITIUM) PER DEVICE.

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Rule amplifies: section 3748.02

Prior effective date: none

3701:1-46-05 CERTAIN MEASURING, GAUGING OR CONTROLLING DEVICES.

- (A) A GENERAL LICENSE IS HEREBY ISSUED TO COMMERCIAL AND INDUSTRIAL FIRMS AND RESEARCH, EDUCATIONAL AND MEDICAL INSTITUTIONS, INDIVIDUALS IN THE CONDUCT OF THEIR BUSINESS, AND STATE OR LOCAL GOVERNMENT AGENCIES TO ACQUIRE, RECEIVE, POSSESS, USE OR TRANSFER, IN ACCORDANCE WITH THE PROVISIONS OF PARAGRAPHS (B), (C) AND (D) OF THIS RULE, BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN DEVICES DESIGNED AND MANUFACTURED FOR THE PURPOSE OF DETECTING, MEASURING, GAUGING OR CONTROLLING THICKNESS, DENSITY, LEVEL, INTERFACE LOCATION, RADIATION, LEAKAGE, OR QUALITATIVE OR QUANTITATIVE CHEMICAL COMPOSITION, OR FOR PRODUCING LIGHT OR AN IONIZED ATMOSPHERE. PERSONS POSSESSING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN DEVICES UNDER THE GENERAL LICENSE IN 10 C.F.R. 31.5 BEFORE JANUARY 15, 1975, MAY CONTINUE TO POSSESS, USE OR TRANSFER THAT MATERIAL IN ACCORDANCE WITH THE REQUIREMENTS OF 10 C.F.R. 31.5 IN EFFECT ON JANUARY 14, 1975.
- (B) (1) THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS RULE APPLIES ONLY TO BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN DEVICES WHICH HAVE BEEN MANUFACTURED OR INITIALLY TRANSFERRED AND LABELED IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN RULE 3701:1-46-30 OF THE ADMINISTRATIVE CODE IN ACCORDANCE WITH:
- (a) A SPECIFIC LICENSE ISSUED UNDER RULE 3701:1-46-30 OF THE ADMINISTRATIVE CODE; OR
 - (b) AN EQUIVALENT SPECIFIC LICENSE ISSUED BY AN AGREEMENT STATE OR NARM LICENSING STATE;
 - (c) AN EQUIVALENT SPECIFIC LICENSE ISSUED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION.
- (2) THE DEVICES MUST HAVE BEEN RECEIVED FROM ONE OF THE SPECIFIC LICENSEES DESCRIBED IN PARAGRAPH (B)(1) OF THIS RULE OR THROUGH A TRANSFER MADE UNDER PARAGRAPH (C)(9) OF THIS RULE:
- (C) ANY PERSON WHO ACQUIRES, RECEIVES, POSSESSES, USES OR TRANSFERS BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN A DEVICE PURSUANT TO THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS RULE:
- (1) SHALL ASSURE THAT ALL LABELS AFFIXED TO THE DEVICE AT THE TIME OF RECEIPT AND BEARING A STATEMENT THAT REMOVAL OF THE LABEL IS PROHIBITED ARE MAINTAINED THEREON AND SHALL COMPLY WITH ALL INSTRUCTIONS AND PRECAUTIONS PROVIDED BY SUCH LABELS;

- (2) SHALL ASSURE THAT THE DEVICE IS TESTED FOR LEAKAGE OF RADIOACTIVE MATERIAL AND PROPER OPERATION OF THE ON-OFF MECHANISM AND INDICATOR, IF ANY, AT NO LONGER THAN SIX-MONTH INTERVALS OR AT SUCH OTHER INTERVALS AS ARE SPECIFIED IN THE LABEL; HOWEVER:
 - (a) DEVICES CONTAINING ONLY KRYPTON NEED NOT BE TESTED FOR LEAKAGE OF RADIOACTIVE MATERIAL, AND
 - (b) DEVICES CONTAINING ONLY TRITIUM OR NOT MORE THAN 3.7 MEGABECQUERELS (ONE HUNDRED MICROCURIES) OF OTHER BETA AND/OR GAMMA EMITTING MATERIAL OR THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) OF ALPHA EMITTING MATERIAL AND DEVICES HELD IN STORAGE IN THE ORIGINAL SHIPPING CONTAINER PRIOR TO INITIAL INSTALLATION NEED NOT BE TESTED FOR ANY PURPOSE;
- (3) SHALL ASSURE THAT THE TESTS REQUIRED BY PARAGRAPH (C)(2) OF THIS RULE AND OTHER TESTING, INSTALLATION, SERVICING, AND REMOVAL FROM INSTALLATION INVOLVING THE RADIOACTIVE MATERIALS, ITS SHIELDING OR CONTAINMENT, ARE PERFORMED:
 - (a) IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED BY THE LABELS; OR
 - (b) BY A PERSON HOLDING A SPECIFIC LICENSE PURSUANT TO CHAPTER 3701:1-40 AND THIS CHAPTER OF THE ADMINISTRATIVE CODE OR FROM AN AGREEMENT STATE, NARM LICENSING STATE OR THE UNITED STATES NUCLEAR REGULATORY COMMISSION TO PERFORM SUCH ACTIVITIES;
- (4) SHALL MAINTAIN RECORDS SHOWING COMPLIANCE WITH THE REQUIREMENTS OF PARAGRAPHS (C)(2) AND (C)(3) OF THIS RULE. THE RECORDS MUST SHOW THE RESULTS OF TESTS. THE RECORDS ALSO MUST SHOW THE DATES OF PERFORMANCE OF, AND THE NAMES OF PERSONS PERFORMING, TESTING, INSTALLING, SERVICING, AND REMOVING FROM THE INSTALLATION RADIOACTIVE MATERIAL AND ITS SHIELDING OR CONTAINMENT. THE LICENSEE SHALL RETAIN THESE RECORDS AS FOLLOWS:
 - (a) EACH RECORD OF A TEST FOR LEAKAGE OR RADIOACTIVE MATERIAL REQUIRED BY PARAGRAPH (C)(2) OF THIS RULE MUST BE RETAINED FOR THREE YEARS AFTER THE NEXT REQUIRED LEAK TEST IS PERFORMED OR UNTIL THE SEALED SOURCE IS TRANSFERRED OR DISPOSED OF.
 - (b) EACH RECORD OF A TEST OF THE ON-OFF MECHANISM AND INDICATOR REQUIRED BY PARAGRAPH (C)(2) OF THIS RULE MUST BE RETAINED FOR THREE YEARS AFTER THE NEXT REQUIRED TEST OF THE ON-OFF MECHANISM AND INDICATOR

IS PERFORMED OR UNTIL THE SEALED SOURCE IS TRANSFERRED OR DISPOSED OF.

- (c) EACH RECORD THAT IS REQUIRED BY PARAGRAPH (C)(3) OF THIS RULE MUST BE RETAINED FOR THREE YEARS FROM THE DATE OF THE RECORDED EVENT OR UNTIL THE DEVICE IS TRANSFERRED OR DISPOSED OF.
- (5) SHALL IMMEDIATELY SUSPEND OPERATION OF THE DEVICE IF THERE IS A FAILURE OF, OR DAMAGE TO, OR ANY INDICATION OF A POSSIBLE FAILURE OF OR DAMAGE TO, THE SHIELDING OF THE RADIOACTIVE MATERIAL OR THE ON-OFF MECHANISM OR INDICATOR, OR UPON THE DETECTION OF ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIES) OR MORE REMOVABLE RADIOACTIVE MATERIAL. THE DEVICE MAY NOT BE OPERATED UNTIL IT HAS BEEN REPAIRED USING REQUIREMENTS IN THE INSTRUCTION MANUAL, BY THE MANUFACTURER OR OTHER PERSON HOLDING A SPECIFIC LICENSE TO REPAIR SUCH DEVICES THAT WAS ISSUED UNDER CHAPTERS 3701:1-40 AND 3701:1-46 OF THE ADMINISTRATIVE CODE OR BY AN AGREEMENT STATE, NARM LICENSING STATE OR THE UNITED STATES NUCLEAR REGULATORY COMMISSION. THE DEVICE MAY BE DISPOSED OF BY TRANSFER TO A PERSON AUTHORIZED BY A SPECIFIC LICENSE TO RECEIVE THE RADIOACTIVE MATERIAL CONTAINED IN THE DEVICE. A REPORT CONTAINING A BRIEF DESCRIPTION OF THE EVENT AND THE REMEDIAL ACTION TAKEN; AND, IN THE CASE OF DETECTION OF ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIE) OR MORE REMOVABLE RADIOACTIVE MATERIAL OR FAILURE OF OR DAMAGE TO A SOURCE LIKELY TO RESULT IN CONTAMINATION OF THE PREMISES OR THE ENVIRONS, A PLAN FOR ENSURING THAT THE PREMISES AND ENVIRONS ARE ACCEPTABLE FOR UNRESTRICTED USE, MUST BE FURNISHED TO THE DIRECTOR WITHIN THIRTY DAYS.
- (6) SHALL NOT ABANDON THE DEVICE CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL OR RADIUM;
- (7) SHALL NOT EXPORT THE DEVICE CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM EXCEPT IN ACCORDANCE WITH 10 C.F.R. 110;
- (8) (a) SHALL TRANSFER OR DISPOSE OF THE DEVICE CONTAINING RADIOACTIVE MATERIAL ONLY BY EXPORT AS PROVIDED BY PARAGRAPH (C)(7) OF THIS RULE, BY TRANSFER TO ANOTHER GENERAL LICENSEE AS AUTHORIZED IN PARAGRAPH (C)(9) OF THIS RULE OR TO A PERSON AUTHORIZED TO RECEIVE THE DEVICE BY A SPECIFIC LICENSE ISSUED UNDER CHAPTERS 3701:1-40 AND THIS CHAPTER OF THE ADMINISTRATIVE CODE, UTILIZING A LICENSED BROKER OR OTHER AUTHORIZED WASTE COLLECTION, OR EQUIVALENT REGULATIONS OF AN AGREEMENT STATE, NARM LICENSING

STATE, UNITED STATES NUCLEAR REGULATORY COMMISSION,
OR AS APPROVED UNDER PARAGRAPH (C)(8)(c) OF THIS RULE.

- (b) SHALL FURNISH A REPORT TO THE DIRECTOR WITHIN THIRTY DAYS AFTER THE TRANSFER OF A DEVICE TO A SPECIFIC LICENSEE. A REPORT IS NOT REQUIRED IF THE DEVICE IS TRANSFERRED TO THE SPECIFIC LICENSEE IN ORDER TO OBTAIN A REPLACEMENT DEVICE FROM THE SAME SPECIFIC LICENSEE. THE REPORT MUST CONTAIN:
 - (i) THE IDENTIFICATION OF THE DEVICE BY MANUFACTURER'S (OR INITIAL TRANSFEROR'S) NAME, MODEL NUMBER, AND SERIAL NUMBER;
 - (ii) THE NAME, ADDRESS, AND LICENSE NUMBER OF THE PERSON RECEIVING THE DEVICE; AND
 - (iii) THE DATE OF THE TRANSFER.
 - (c) SHALL OBTAIN WRITTEN DIRECTOR APPROVAL BEFORE TRANSFERRING THE DEVICE TO ANY OTHER SPECIFIC LICENSEE NOT SPECIFICALLY IDENTIFIED IN PARAGRAPH (C)(8)(a) OF THIS RULE.
- (9) SHALL TRANSFER THE DEVICE TO ANOTHER GENERAL LICENSEE ONLY IF:
- (a) THE DEVICE REMAINS IN USE AT A PARTICULAR LOCATION. IN THIS CASE, THE TRANSFEROR SHALL GIVE THE TRANSFEREE A COPY OF THIS RULE AND ANY SAFETY DOCUMENTS IDENTIFIED IN THE LABEL OF THE DEVICE. WITHIN THIRTY DAYS OF THE TRANSFER, THE TRANSFEROR SHALL REPORT TO THE DEPARTMENT:
 - (i) THE MANUFACTURER'S (OR INITIAL TRANSFEROR'S) NAME;
 - (ii) THE MODEL NUMBER AND THE SERIAL NUMBER OF THE DEVICE TRANSFERRED;
 - (iii) THE TRANSFEREE'S NAME AND MAILING ADDRESS FOR THE LOCATION OF USE; AND
 - (iv) THE NAME, TITLE, AND PHONE NUMBER OF THE RESPONSIBLE INDIVIDUAL IDENTIFIED BY THE TRANSFEREE IN ACCORDANCE WITH PARAGRAPH (C)(11) OF THIS RULE TO HAVE KNOWLEDGE OF AND AUTHORITY TO TAKE ACTIONS TO ENSURE COMPLIANCE WITH THE APPROPRIATE RULES AND REQUIREMENTS; OR

- (b) THE DEVICE IS HELD IN STORAGE BY AN INTERMEDIATE PERSON IN THE ORIGINAL SHIPPING CONTAINER AT ITS INTENDED LOCATION OF USE PRIOR TO INITIAL USE BY A GENERAL LICENSEE.
- (10) SHALL COMPLY WITH THE PROVISIONS OF PARAGRAPHS (A) AND (B) OF RULE 3701:1-38-21 OF THE ADMINISTRATIVE CODE FOR REPORTING RADIATION INCIDENTS, THEFT OR LOSS OF LICENSED MATERIAL, BUT SHALL BE EXEMPT FROM THE OTHER REQUIREMENTS OF CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE.
- (11) SHALL APPOINT AN INDIVIDUAL RESPONSIBLE FOR HAVING KNOWLEDGE OF THE APPROPRIATE RULES AND REQUIREMENTS AND THE AUTHORITY FOR TAKING REQUIRED ACTIONS TO COMPLY WITH APPROPRIATE RULES AND REQUIREMENTS. THE GENERAL LICENSEE, THROUGH THIS INDIVIDUAL, SHALL ENSURE THE DAY-TO-DAY COMPLIANCE WITH APPROPRIATE RULES AND REQUIREMENTS. THIS APPOINTMENT DOES NOT RELIEVE THE GENERAL LICENSEE OF RESPONSIBILITY IN THIS REGARD.
- (12) (a) SHALL REPORT, IN ACCORDANCE WITH PARAGRAPHS (C)(12)(b) AND (c) OF THIS RULE, DEVICES CONTAINING AT LEAST THREE HUNDRED SEVENTY MBQ (TEN MCI) OF CESIUM-137, 3.7 MBQ (0.1 MCI) OF STRONTIUM-90, THIRTY SEVEN MBQ (ONE MCI) OF COBALT-60, 3.7 KBQ (0.1 μCI) OF RADIUM, OR THIRTY SEVEN MBQ (ONE MCI) OF AMERICIUM-241 OR ANY OTHER TRANSURANIC, i.e., ELEMENT WITH ATOMIC NUMBER GREATER THAN URANIUM (92), BASED ON THE ACTIVITY INDICATED ON THE LABEL. EACH ADDRESS FOR A LOCATION OF USE, AS DESCRIBED UNDER PARAGRAPH (C)(12)(c)(iv), REPRESENTS A SEPARATE GENERAL LICENSE.
- (b) IF IN POSSESSION OF A DEVICE MEETING THE CRITERIA OF PARAGRAPH (C)(12)(a) OF THIS RULE, SHALL REPORT THESE DEVICES ANNUALLY TO THE DIRECTOR AND IS SUBJECT TO THE FEES IN PARAGRAPH (U) OF RULE 3701-38-02.1 OF THE ADMINISTRATIVE CODE. REPORTING MUST BE DONE BY VERIFYING, CORRECTING, AND/OR ADDING TO THE INFORMATION CONTAINED IN A REQUEST PROVIDED BY THE DIRECTOR. THE INFORMATION MUST BE SUBMITTED TO THE DIRECTOR WITHIN THIRTY DAYS OF THE DATE OF THE REQUEST FOR INFORMATION OR AS OTHERWISE INDICATED IN THE REQUEST. IN ADDITION, A GENERAL LICENSEE HOLDING DEVICES MEETING THE CRITERIA OF PARAGRAPH (C)(12)(a) OF THIS RULE IS SUBJECT TO THE BANKRUPTCY NOTIFICATION REQUIREMENT IN CHAPTER 3701:1-40 OF THE ADMINISTRATIVE CODE.

- (c) IN REPORTING THE DEVICES, THE GENERAL LICENSEE SHALL FURNISH THE FOLLOWING INFORMATION AND ANY OTHER INFORMATION SPECIFICALLY REQUESTED BY THE DIRECTOR:
 - (i) NAME AND MAILING ADDRESS OF THE GENERAL LICENSEE.
 - (ii) INFORMATION ABOUT EACH DEVICE: THE MANUFACTURER (OR INITIAL TRANSFEROR), MODEL NUMBER, SERIAL NUMBER, THE RADIOISOTOPE AND ACTIVITY (AS INDICATED ON THE LABEL).
 - (iii) NAME AND TELEPHONE NUMBER OF THE RESPONSIBLE PERSON DESIGNATED AS A REPRESENTATIVE OF THE GENERAL LICENSEE UNDER PARAGRAPH (C)(11) OF THIS RULE.
 - (iv) ADDRESS AT WHICH THE DEVICE(S) ARE USED AND/OR STORED.
 - (v) CERTIFICATION BY THE RESPONSIBLE REPRESENTATIVE OF THE GENERAL LICENSEE THAT THE INFORMATION CONCERNING THE DEVICE(S) HAS BEEN VERIFIED THROUGH A PHYSICAL INVENTORY AND CHECKING OF LABEL INFORMATION.
 - (vi) CERTIFICATION BY THE RESPONSIBLE REPRESENTATIVE OF THE GENERAL LICENSEE THAT THEY ARE AWARE OF THE REQUIREMENTS OF THE GENERAL LICENSE.
- (13) SHALL REPORT CHANGES OF ADDRESS (INCLUDING CHANGE IN NAME OF GENERAL LICENSEE) TO THE DIRECTOR WITHIN THIRTY DAYS OF THE EFFECTIVE DATE OF THE CHANGE.
- (14) MAY NOT HOLD DEVICES THAT ARE NOT IN USE FOR LONGER THAN TWO YEARS. IF DEVICES WITH SHUTTERS ARE NOT BEING USED, THE SHUTTER MUST BE LOCKED IN THE CLOSED POSITION. THE TESTING REQUIRED BY PARAGRAPH (C)(2) OF THIS RULE NEED NOT BE PERFORMED DURING THE PERIOD OF STORAGE ONLY. HOWEVER, WHEN DEVICES ARE PUT BACK INTO SERVICE OR TRANSFERRED TO ANOTHER PERSON, AND HAVE NOT BEEN TESTED WITHIN THE REQUIRED TEST INTERVAL, THEY MUST BE TESTED FOR LEAKAGE BEFORE USE OR TRANSFER AND THE SHUTTER TESTED BEFORE USE. DEVICES KEPT IN STANDBY FOR FUTURE USE ARE EXCLUDED FROM THE TWO YEAR TIME LIMIT IF THE GENERAL LICENSEE PERFORMS QUARTERLY PHYSICAL INVENTORIES OF THESE DEVICES WHILE THEY ARE IN STANDBY.

- (D) THE DIRECTOR MAY ORDER THE INSPECTION OF ANY FACILITY LICENSED UNDER THIS RULE IF THE DIRECTOR DETERMINES THAT AN APPROPRIATE REASON FOR THE INSPECTION EXISTS. THESE INSPECTIONS SHALL BE CONSIDERED AS FULL COST INSPECTIONS AS DEFINED IN RULE 3701-38-02.1 OF THE ADMINISTRATIVE CODE. THE REASONS THE DIRECTOR MAY CONDUCT FOR CAUSE INSPECTIONS INCLUDE, BUT ARE NOT LIMITED TO,
 - (1) FAILURE TO RESPOND TO OFFICIAL CORRESPONDENCE,
 - (2) RELEASE OF RADIOACTIVE MATERIAL TO THE ENVIRONMENT,
 - (3) INVESTIGATIONS OF ALLEGED VIOLATIONS OF DEPARTMENT RULES, OR
 - (4) FAILURE TO COMPLY WITH THE LICENSE APPLICATION PROCESS.
- (E) ALL PORTABLE DEVICES CONTAINING RADIOACTIVE MATERIAL, USED WITHIN THE STATE OF OHIO, SHALL BE LICENSED IN ACCORDANCE WITH RULES 3701-38-02.1 AND PARAGRAPH (I) OF RULE 3701:1-40-14 OF THE ADMINISTRATIVE CODE.
- (F) THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS RULE DOES NOT AUTHORIZE THE MANUFACTURE OR IMPORT OF DEVICES CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL OR RADIUM.

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3701:1-46-06 LICENSE TO INSTALL DEVICES THAT ARE GENERALLY LICENSED

ANY PERSON WHO HOLDS A SPECIFIC LICENSE ISSUED BY THE NUCLEAR REGULATORY COMMISSION, AN AGREEMENT STATE, OR NARM LICENSING STATE AUTHORIZING THE HOLDER TO MANUFACTURE, INSTALL, OR SERVICE A DEVICE DESCRIBED IN RULE 3701:1-46-05 OF THE ADMINISTRATIVE CODE IS HEREBY GRANTED A GENERAL LICENSE TO INSTALL AND SERVICE SUCH DEVICE PROVIDED THAT:

- (A) THE DEVICE HAS BEEN MANUFACTURED, LABELED, INSTALLED, AND SERVICED IN ACCORDANCE WITH APPLICABLE PROVISIONS OF THE SPECIFIC LICENSE ISSUED SUCH PERSON BY THE NUCLEAR REGULATORY COMMISSION, AN AGREEMENT STATE, OR NARM LICENSING STATE AND REQUIREMENTS OF PARAGRAPH (C)(2) OF RULE 3701-38-02.1 OF THE ADMINISTRATIVE CODE.
- (B) SUCH PERSON ASSURES THAT ANY LABELS REQUIRED TO BE AFFIXED TO THE DEVICE UNDER REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION, AN AGREEMENT STATE, OR NARM LICENSING STATE WHICH LICENSED THE MANUFACTURER OF THE DEVICE, BEAR A STATEMENT THAT REMOVAL OF THE LABEL IS PROHIBITED.

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3701:1-46-07 LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT.

- (A) A GENERAL LICENSE IS HEREBY ISSUED TO OWN, RECEIVE, ACQUIRE, POSSESS, AND USE TRITIUM OR PROMETHIUM-147 CONTAINED IN LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT, PROVIDED EACH DEVICE CONTAINS NOT MORE THAN 0.37 TERABECQUERELS (TEN CURIES) OF TRITIUM OR 11.1 GIGABECQUERELS (THREE HUNDRED MILLICURIES) OF PROMETHIUM-147 AND THAT EACH DEVICE HAS BEEN MANUFACTURED, ASSEMBLED OR INITIALLY TRANSFERRED IN ACCORDANCE WITH A LICENSE ISSUED UNDER THE PROVISIONS OF RULE 3701:1-46-33 OF THIS CHAPTER OR MANUFACTURED OR ASSEMBLED IN ACCORDANCE WITH A SPECIFIC LICENSE ISSUED BY THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE WHICH AUTHORIZES MANUFACTURE OR ASSEMBLY OF THE DEVICE FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED BY THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE.
- (B) PERSONS WHO OWN, RECEIVE, ACQUIRE, POSSESS OR USE LUMINOUS SAFETY DEVICES PURSUANT TO THE GENERAL LICENSE IN THIS RULE ARE EXEMPT FROM THE REQUIREMENTS OF CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE EXCEPT THAT THEY SHALL COMPLY WITH THE PROVISIONS OF PARAGRAPHS (A) AND (B) OF RULE 3701:1-38-21 OF THE ADMINISTRATIVE CODE.
- (C) THIS GENERAL LICENSE DOES NOT AUTHORIZE THE MANUFACTURE, ASSEMBLY, REPAIR OR IMPORT OF LUMINOUS SAFETY DEVICES CONTAINING TRITIUM OR PROMETHIUM-147.
- (D) THIS GENERAL LICENSE DOES NOT AUTHORIZE THE EXPORT OF LUMINOUS SAFETY DEVICES CONTAINING TRITIUM OR PROMETHIUM-147.
- (E) THIS GENERAL LICENSE DOES NOT AUTHORIZE THE OWNERSHIP, RECEIPT, ACQUISITION, POSSESSION OR USE OF PROMETHIUM-147 CONTAINED IN INSTRUMENT DIALS.

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3701:1-46-08 AMERICIUM-241 OR RADIUM IN THE FORM OF CALIBRATION OR REFERENCE SOURCES.

- (A) A GENERAL LICENSE IS HEREBY ISSUED TO THOSE PERSONS LISTED BELOW TO OWN, RECEIVE, ACQUIRE, POSSESS, USE AND TRANSFER, IN ACCORDANCE WITH THE PROVISIONS OF PARAGRAPHS (B) AND (C) OF THIS RULE, AMERICIUM-241 OR RADIUM IN THE FORM OF CALIBRATION OR REFERENCE SOURCES.
- (B) THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS RULE APPLIES ONLY TO CALIBRATION OR REFERENCE SOURCES WHICH HAVE BEEN MANUFACTURED OR INITIALLY TRANSFERRED IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN A SPECIFIC LICENSE ISSUED PURSUANT TO RULE 3701:1-46-37 OF THIS CHAPTER OR IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN A SPECIFIC LICENSE ISSUED TO THE MANUFACTURER BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION, ANOTHER AGREEMENT STATE, OR NARM LICENSING STATE FOR RADIUM WHICH AUTHORIZES MANUFACTURE OF THE SOURCES FOR DISTRIBUTION TO PERSONS WITH A GENERAL LICENSE BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION, ANOTHER AGREEMENT STATE, OR NARM LICENSING STATE FOR RADIUM.
- (C) THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS RULE IS SUBJECT TO THE PROVISIONS OF RULES 3701:1-38-09, PARAGRAPH (D) OF 3701:1-40-08, PARAGRAPHS (A) TO (C) OF 3401:1-40-16, 3701:1-40-19, 3701:1-40-20, 3701:1-40-21, AND 3701:1-38-06 OF THE ADMINISTRATIVE CODE AND CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE. IN ADDITION, PERSONS WHO OWN, RECEIVE, ACQUIRE, POSSESS, USE AND TRANSFER ONE OR MORE CALIBRATION OR REFERENCE SOURCES PURSUANT TO THIS GENERAL LICENSE:
- (1) SHALL NOT POSSESS AT ANY ONE TIME, AT ANY ONE LOCATION OF STORAGE OR USE, MORE THAN ONE HUNDRED EIGHTY FIVE KILOBECQUERELS (FIVE MICROCURIES) OF AMERICIUM-241 OR RADIUM IN SUCH SOURCES:
- (2) SHALL NOT RECEIVE, POSSESS, USE OR TRANSFER SUCH SOURCE UNLESS THE SOURCE, OR THE STORAGE CONTAINER, BEARS A LABEL WHICH INCLUDES THE FOLLOWING STATEMENT OR A SUBSTANTIALLY SIMILAR STATEMENT WHICH CONTAINS THE INFORMATION CALLED FOR IN THE FOLLOWING STATEMENT:
- (a) THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS SOURCE, MODEL __, SERIAL NO. __, ARE SUBJECT TO A GENERAL LICENSE AND THE REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR OF A STATE WITH WHICH THE COMMISSION HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. DO NOT REMOVE THIS LABEL.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

(NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

OR FOR RADIUM;

- (b) THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS SOURCE, MODEL_____, SERIAL NO. _____, ARE SUBJECT TO A GENERAL LICENSE AND THE REGULATIONS OF A NARM LICENSING STATE. DO NOT REMOVE THIS LABEL.

CAUTION - RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS RADIUM. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

SOURCES GENERALLY LICENSED UNDER THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE PRIOR TO JANUARY 19, 1975 MAY BEAR LABELS AUTHORIZED BY THE NUCLEAR REGULATORY COMMISSION REGULATIONS IN EFFECT ON JANUARY 1, 1975.

- (3) SHALL NOT TRANSFER, ABANDON, OR DISPOSE OF SUCH SOURCE EXCEPT BY TRANSFER TO A PERSON AUTHORIZED BY A LICENSE PURSUANT TO THIS CHAPTER OR FROM AN AGREEMENT STATE, THE UNITED STATES NUCLEAR REGULATORY COMMISSION, OR A NARM LICENSING STATE TO RECEIVE THE SOURCE.
- (4) SHALL STORE SUCH SOURCE, EXCEPT WHEN THE SOURCE IS BEING USED, IN A CLOSED CONTAINER ADEQUATELY DESIGNED AND CONSTRUCTED TO CONTAIN EITHER AMERICIUM-241 OR RADIUM, AS APPLICABLE WHICH MIGHT OTHERWISE ESCAPE DURING STORAGE.
- (5) SHALL NOT USE SUCH SOURCE FOR ANY PURPOSE OTHER THAN THE CALIBRATION OF RADIATION DETECTORS OR THE STANDARDIZATION OF OTHER SOURCES.
- (D) THIS GENERAL LICENSE DOES NOT AUTHORIZE THE MANUFACTURE OR IMPORT OF CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM.
- (E) THIS GENERAL LICENSE DOES NOT AUTHORIZE THE EXPORT OF CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM.

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3701:1-46-09 GENERAL LICENSE TO OWN BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM.

A GENERAL LICENSE IS HEREBY ISSUED TO OWN BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM WITHOUT REGARD TO QUANTITY. NOTWITHSTANDING ANY OTHER PROVISION OF THIS CHAPTER, A GENERAL LICENSEE UNDER THIS PARAGRAPH IS NOT AUTHORIZED TO MANUFACTURE, PRODUCE, TRANSFER, RECEIVE, POSSESS, USE, IMPORT OR EXPORT BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL, EXCEPT AS AUTHORIZED IN A SPECIFIC LICENSE.

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3701:1-46-10 GENERAL LICENSE FOR STRONTIUM-90 IN ICE DETECTION DEVICES.

- (A) A GENERAL LICENSE IS HEREBY ISSUED TO OWN, RECEIVE, ACQUIRE, POSSESS, USE, AND TRANSFER STRONTIUM-90 CONTAINED IN ICE DETECTION DEVICES, PROVIDED EACH DEVICE CONTAINS NOT MORE THAN 1.85 MEGABECQUERELS (FIFTY MICROCURIES) OF STRONTIUM-90 AND EACH DEVICE HAS BEEN MANUFACTURED OR INITIALLY TRANSFERRED IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN A LICENSE ISSUED PURSUANT TO RULE 3701:1-46-40 OF THIS CHAPTER OR IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN A SPECIFIC LICENSE ISSUED TO THE MANUFACTURER BY THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE WHICH AUTHORIZES MANUFACTURE OF THE ICE DETECTION DEVICES FOR DISTRIBUTION TO PERSONS WITH A GENERAL LICENSE ISSUED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE.
- (B) PERSONS WHO OWN, RECEIVE, ACQUIRE, POSSESS, USE, OR TRANSFER STRONTIUM-90 CONTAINED IN ICE DETECTION DEVICES PURSUANT TO THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS SECTION:
- (1) SHALL, UPON OCCURRENCE OF VISUALLY OBSERVABLE DAMAGE, SUCH AS A BEND OR CRACK OR DISCOLORATION FROM OVERHEATING, TO THE DEVICE, DISCONTINUE USE OF THE DEVICE UNTIL IT HAS BEEN INSPECTED, TESTED FOR LEAKAGE AND REPAIRED BY A PERSON HOLDING A SPECIFIC LICENSE PURSUANT TO RULE 3701-38-02.1 AND CHAPTERS 3701:1-40 AND 3701:1-46 OF THE ADMINISTRATIVE CODE OR FROM THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE TO MANUFACTURE OR SERVICE SUCH DEVICES; OR SHALL DISPOSE OF THE DEVICE PURSUANT TO THE PROVISIONS OF PARAGRAPH (A) OF RULE 3701:1-38-19 OF THE ADMINISTRATIVE CODE.
 - (2) SHALL ASSURE THAT ALL LABELS AFFIXED TO THE DEVICE AT THE TIME OF RECEIPT, AND WHICH BEAR A STATEMENT WHICH PROHIBITS REMOVAL OF THE LABELS, ARE MAINTAINED THEREON;
 - (3) ARE EXEMPT FROM THE REQUIREMENTS OF CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE EXCEPT THAT SUCH PERSONS SHALL COMPLY WITH THE PROVISIONS OF PARAGRAPH (A) OF RULE 3701:1-38-19 OF THE ADMINISTRATIVE CODE AND PARAGRAPHS (A) AND (B) OF RULE 3701:1-38-21 OF THE ADMINISTRATIVE CODE.
- (C) THE GENERAL LICENSE DOES NOT AUTHORIZE THE MANUFACTURE, ASSEMBLY, DISASSEMBLY, REPAIR, OR IMPORT OF STRONTIUM-90 IN ICE DETECTION DEVICES.

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3701:1-46-11 GENERAL LICENSE FOR USE OF EITHER BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL FOR CERTAIN IN VITRO CLINICAL OR LABORATORY TESTING.

(A) A GENERAL LICENSE IS HEREBY ISSUED TO ANY PHYSICIAN, VETERINARIAN IN THE PRACTICE OF VETERINARY MEDICINE, CLINICAL LABORATORY OR HOSPITAL TO RECEIVE, ACQUIRE, POSSESS, TRANSFER, OR USE, FOR ANY OF THE FOLLOWING STATED TESTS, IN ACCORDANCE WITH THE PROVISIONS OF PARAGRAPHS (B), (C), (D), (E), AND (F) OF THIS RULE, THE FOLLOWING BYPRODUCT OR ACCELERATOR PRODUCED MATERIALS IN PREPACKAGED UNITS:

- (1) IODINE-125, IN UNITS NOT EXCEEDING THREE HUNDRED-SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.
- (2) IODINE-131, IN UNITS NOT EXCEEDING THREE HUNDRED-SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.
- (3) CARBON-14, IN UNITS NOT EXCEEDING THREE HUNDRED-SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.
- (4) HYDROGEN-3 (TRITIUM), IN UNITS NOT EXCEEDING 1.85 MEGABECQUERELS (FIFTY MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.
- (5) IRON-59, IN UNITS NOT EXCEEDING SEVEN HUNDRED-FORTY KILOBECQUERELS (TWENTY MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS, OR ANIMALS.
- (6) SELENIUM-75, IN UNITS NOT EXCEEDING THREE HUNDRED-SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.
- (7) MOCK IODINE-125 REFERENCE OR CALIBRATION SOURCES, IN UNITS NOT EXCEEDING 1.85 KILOBECQUERELS (.05 MICROCURIES) OF IODINE-129 AND ONE HUNDRED-EIGHTY-FIVE BECQUERELS (.005

MICROCURIES) OF AMERICIUM-241 EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF BYPRODUCT MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.

- (8) COBALT-57, IN UNITS NOT EXCEEDING THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH FOR USE IN IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF ACCELERATOR PRODUCED MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS.
- (B) A PERSON SHALL NOT RECEIVE, ACQUIRE, POSSESS, USE, OR TRANSFER BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL UNDER THE GENERAL LICENSE ESTABLISHED BY PARAGRAPH (A) OF THIS RULE UNLESS THAT PERSON:
- (1) HAS FILED THE RADIOACTIVE MATERIALS IN VITRO TESTING FORM WITH THE DIRECTOR; OR
 - (2) HAS A LICENSE THAT AUTHORIZES THE MEDICAL USE OF BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL THAT WAS ISSUED UNDER RULES FOR MEDICAL USES OF RADIOACTIVE MATERIAL.
- (C) A PERSON WHO RECEIVES, ACQUIRES, POSSESSES, OR USES BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL PURSUANT TO THE GENERAL LICENSE ESTABLISHED BY PARAGRAPH (A) OF THIS RULE SHALL COMPLY WITH THE FOLLOWING:
- (1) THE GENERAL LICENSEE SHALL NOT POSSESS AT ANY ONE TIME, PURSUANT TO THE GENERAL LICENSE IN PARAGRAPH (A) OF THIS RULE, AT ANY ONE LOCATION OF STORAGE OR USE, A TOTAL AMOUNT OF IODINE-125, IODINE-131, SELENIUM-75, IRON-59, AND/OR COBALT-57 IN EXCESS OF 7.4 MEGABECQUERELS (TWO HUNDRED MICROCURIES).
 - (2) THE GENERAL LICENSEE SHALL STORE THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL, UNTIL USED, IN THE ORIGINAL SHIPPING CONTAINER OR IN A CONTAINER PROVIDING EQUIVALENT RADIATION PROTECTION.
 - (3) THE GENERAL LICENSEE SHALL USE THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL ONLY FOR THE USES AUTHORIZED BY PARAGRAPH (A) OF THIS RULE.
 - (4) THE GENERAL LICENSEE SHALL NOT TRANSFER THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL EXCEPT BY TRANSFER TO A PERSON AUTHORIZED TO RECEIVE IT BY A LICENSE PURSUANT TO THIS CHAPTER, FROM THE UNITED STATES NUCLEAR REGULATORY COMMISSION, FROM AN AGREEMENT STATE, OR A NARM LICENSING

STATE OR TRANSFER THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL IN ANY MANNER OTHER THAN IN THE UNOPENED, LABELED SHIPPING CONTAINER AS RECEIVED FROM THE SUPPLIER.

- (5) THE GENERAL LICENSEE SHALL DISPOSE OF THE MOCK IODINE-125 REFERENCE OR CALIBRATION SOURCES DESCRIBED IN PARAGRAPH (A)(7) OF THIS RULE AS REQUIRED BY RULE 3701:1-38-19 OF THE ADMINISTRATIVE CODE.
- (D) THE GENERAL LICENSEE SHALL NOT RECEIVE, ACQUIRE, POSSESS OR USE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL PURSUANT TO PARAGRAPH (A) OF THIS RULE:
- (1) EXCEPT AS PREPACKAGED UNITS WHICH ARE LABELED IN ACCORDANCE WITH THE PROVISIONS OF A SPECIFIC LICENSE ISSUED UNDER THE PROVISIONS OF RULE 3701:1-46-42 OF THIS CHAPTER OR IN ACCORDANCE WITH THE PROVISIONS OF A SPECIFIC LICENSE ISSUED BY THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE THAT AUTHORIZES MANUFACTURE AND DISTRIBUTION OF IODINE-125, IODINE-131, CARBON-14, HYDROGEN-3 (TRITIUM), SELENIUM-75, IRON-59, MOCK IODINE-125, OR A NARM LICENSING STATE THAT AUTHORIZES MANUFACTURE AND DISTRIBUTION OF COBALT-57 FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED BY THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE.
- (2) UNLESS THE FOLLOWING STATEMENT, OR A SUBSTANTIALLY SIMILAR STATEMENT WHICH CONTAINS THE INFORMATION CALLED FOR IN THE FOLLOWING STATEMENT, APPEARS ON A LABEL AFFIXED TO EACH PREPACKAGED UNIT OR APPEARS IN A LEAFLET OR BROCHURE WHICH ACCOMPANIES THE PACKAGE:
- (a) THIS RADIOACTIVE MATERIAL MAY BE RECEIVED, ACQUIRED, POSSESSED, AND USED ONLY BY PHYSICIANS, VETERINARIANS IN THE PRACTICE OF VETERINARY MEDICINE, CLINICAL LABORATORIES OR HOSPITALS AND ONLY FOR IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF THE MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS. ITS RECEIPT, ACQUISITION, POSSESSION, USE, AND TRANSFER ARE SUBJECT TO THE REGULATIONS AND A GENERAL LICENSE OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR OF A STATE WITH WHICH THE COMMISSION HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY
_____ (NAME OF MANUFACTURER)

OR FOR NARM;

(b) THIS RADIOACTIVE MATERIAL MAY BE RECEIVED, ACQUIRED, POSSESSED, AND USED ONLY BY PHYSICIANS, VETERINARIANS IN THE PRACTICE OF VETERINARY MEDICINE, CLINICAL LABORATORIES OR HOSPITALS AND ONLY FOR IN-VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF THE MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS. ITS RECEIPT, ACQUISITION, POSSESSION, USE, AND TRANSFER ARE SUBJECT TO THE REGULATIONS AND A GENERAL LICENSE OF A NARM LICENSING STATE.

_____ (NAME OF MANUFACTURER)

(E) THE LICENSEE POSSESSING OR USING BYPRODUCT OR ACCELERATOR PRODUCED MATERIALS UNDER THE GENERAL LICENSE OF PARAGRAPH (A) OF THIS RULE SHALL REPORT IN WRITING TO THE DIRECTOR ANY CHANGES IN THE INFORMATION FURNISHED BY THE LICENSEE IN THE "REGISTRATION CERTIFICATE IN-VITRO TESTING WITH BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL UNDER GENERAL LICENSE". THE REPORT SHALL BE FURNISHED WITHIN THIRTY DAYS AFTER THE EFFECTIVE DATE OF SUCH CHANGE.

(F) ANY PERSON USING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL PURSUANT TO THE GENERAL LICENSE OF PARAGRAPH (A) OF THIS RULE IS EXEMPT FROM THE REQUIREMENTS OF CHAPTER 3701:1-38 OF THE ADMINISTRATIVE CODE WITH RESPECT TO BYPRODUCT OR ACCELERATOR PRODUCED MATERIALS COVERED BY THAT GENERAL LICENSE, EXCEPT THAT SUCH PERSONS USING THE MOCK IODINE-125 DESCRIBED IN PARAGRAPH (A)(7) OF THIS RULE SHALL COMPLY WITH THE PROVISIONS OF PARAGRAPH (A) OF RULE 3701:1-38-19 OF THE ADMINISTRATIVE CODE AND PARAGRAPHS (A) AND (B) OF RULE 3701:1-38-21 OF THE ADMINISTRATIVE CODE.

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3701:1-46-12 MAINTENANCE OF RECORDS.

EACH RECORD REQUIRED BY THIS CHAPTER MUST BE LEGIBLE THROUGHOUT THE RETENTION PERIOD SPECIFIED BY THE DIRECTOR. THE RECORD MAY BE THE ORIGINAL OR A REPRODUCED COPY OR A MICROFORM PROVIDED THAT THE COPY OR MICROFORM IS AUTHENTICATED BY AUTHORIZED PERSONNEL AND THAT THE MICROFORM IS CAPABLE OF PRODUCING A CLEAR COPY THROUGHOUT THE REQUIRED RETENTION PERIOD. THE RECORD MAY ALSO BE STORED IN ELECTRONIC MEDIA WITH THE CAPABILITY FOR PRODUCING LEGIBLE, ACCURATE, AND COMPLETE RECORDS DURING THE REQUIRED RETENTION PERIOD. RECORDS SUCH AS LETTERS, DRAWINGS, SPECIFICATIONS, MUST INCLUDE ALL PERTINENT INFORMATION SUCH AS LETTERS, STAMPS, INITIALS, AND SIGNATURES. THE LICENSEE SHALL MAINTAIN ADEQUATE SAFEGUARDS AGAINST TAMPERING WITH AND LOSS OF RECORDS.

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3701:1-46-13 INTRODUCTION OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN EXEMPT CONCENTRATIONS INTO PRODUCTS OR MATERIALS, AND TRANSFER OF OWNERSHIP OR POSSESSION OF ACCELERATOR PRODUCED MATERIAL OR RADIUM IN EXEMPT CONCENTRATIONS: REQUIREMENTS FOR LICENSE.

- (A) AN APPLICATION FOR A SPECIFIC LICENSE ON FORMS PROVIDED BY THE DIRECTOR AUTHORIZING THE INTRODUCTION OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM INTO A PRODUCT OR MATERIAL OWNED BY OR IN THE POSSESSION OF THE LICENSEE OR ANOTHER AND THE TRANSFER OF OWNERSHIP OR POSSESSION OF THE PRODUCT OR MATERIAL CONTAINING ACCELERATOR PRODUCED MATERIAL OR RADIUM WILL BE APPROVED IF THE APPLICANT:
- (1) SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
 - (2) PROVIDES A DESCRIPTION OF THE PRODUCT OR MATERIAL INTO WHICH THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM WILL BE INTRODUCED, INTENDED USE OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM AND THE PRODUCT OR MATERIAL INTO WHICH IT IS INTRODUCED, METHOD OF INTRODUCTION, INITIAL CONCENTRATION OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN THE PRODUCT OR MATERIAL, CONTROL METHODS TO ASSURE THAT NO MORE THAN THE SPECIFIED CONCENTRATION IS INTRODUCED INTO THE PRODUCT OR MATERIAL, ESTIMATED TIME INTERVAL BETWEEN INTRODUCTION AND TRANSFER OF THE PRODUCT OR MATERIAL, AND ESTIMATED CONCENTRATION OF THE RADIONUCLIDES IN THE PRODUCT OR MATERIAL AT THE TIME OF TRANSFER; AND
 - (3) PROVIDES REASONABLE ASSURANCE THAT THE CONCENTRATIONS OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM AT THE TIME OF TRANSFER WILL NOT EXCEED THE CONCENTRATIONS IN RULE 3701:1-40-08 OF THE ADMINISTRATIVE CODE, THAT RECONCENTRATION OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN CONCENTRATIONS EXCEEDING THOSE IN RULE 3701:1-40-08 OF THE ADMINISTRATIVE CODE IS NOT LIKELY, THAT USE OF LOWER CONCENTRATIONS IS NOT FEASIBLE, AND THAT THE PRODUCT OR MATERIAL IS NOT LIKELY TO BE INCORPORATED IN ANY FOOD, BEVERAGE, COSMETIC, DRUG OR OTHER COMMODITY OR PRODUCT DESIGNED FOR INGESTION OR INHALATION BY, OR APPLICATION TO, A HUMAN BEING.
- (B) MANUFACTURE OF THE PRODUCT OR MATERIAL WILL BE THROUGH A SPECIFIC LICENSE ISSUED BY THE DEPARTMENT.
- (C) TRANSFER OF BYPRODUCT MATERIAL TO PERSONS EXEMPT FROM LICENCING IN ACCORDANCE WITH RULE 3701:1-40-08 OF THE ADMINISTRATIVE CODE WILL BE IN ACCORDANCE WITH A LICENSE ISSUED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION PURSUANT TO 10 CFR 32.11.

- (D) TRANSFER OF ACCELERATOR PRODUCED MATERIAL TO PERSONS EXEMPT FROM LICENCING IN ACCORDANCE WITH RULE 3701:1-40-08 OF THE ADMINISTRATIVE CODE WILL REQUIRE A DISTRIBUTION LICENSE.

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R.C. 119.032 review date:

Certified by:

Jodi Govern, Secretary
Public Health Council

Date

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3701:1-46-14 INTRODUCTION OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN EXEMPT CONCENTRATIONS INTO PRODUCTS OR MATERIALS, AND TRANSFER OF OWNERSHIP OR POSSESSION OF ACCELERATOR PRODUCED MATERIAL OR RADIUM IN EXEMPT CONCENTRATIONS: RECORDS AND MATERIAL TRANSFER REPORTS.

- (A) EACH PERSON LICENSED UNDER RULE 3701:1-46-13 OF THE ADMINISTRATIVE CODE SHALL MAINTAIN RECORDS OF TRANSFER OF MATERIAL AND FILE A REPORT WITH THE

OHIO DEPARTMENT OF HEALTH, BUREAU OF RADIATION PROTECTION

35 EAST CHESTNUT STREET, SEVENTH FLOOR

POST OFFICE BOX 118

COLUMBUS, OHIO 43216-0118

- (B) THE REPORT MUST IDENTIFY THE:

- (1) TYPE AND QUANTITY OF EACH PRODUCT OR MATERIAL INTO WHICH BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM HAS BEEN INTRODUCED DURING THE REPORTING PERIOD;
- (2) NAME AND ADDRESS OF THE PERSON WHO OWNED OR POSSESSED THE PRODUCT OR MATERIAL, INTO WHICH BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM HAS BEEN INTRODUCED, AT THE TIME OF INTRODUCTION;
- (3) THE TYPE AND QUANTITY OF RADIONUCLIDE INTRODUCED INTO EACH PRODUCT OR MATERIAL; AND
- (4) THE INITIAL CONCENTRATIONS OF THE RADIONUCLIDE IN THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM AT TIME OF TRANSFER OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM BY THE LICENSEE.

- (C) THE LICENSEE SHALL FILE THE REPORT WITHIN THIRTY DAYS FOLLOWING:

- (1) FIVE YEARS AFTER FILING THE PRECEDING REPORT; OR
- (2) FILING AN APPLICATION FOR RENEWAL OF THE LICENSE PURSUANT TO RULE 3701-38-02.1 OF THE ADMINISTRATIVE CODE; OR
- (3) NOTIFYING THE DIRECTOR, UNDER RULE 3701:1-40-16 OF THE ADMINISTRATIVE CODE, OF THE LICENSEE'S DECISION TO PERMANENTLY DISCONTINUE ACTIVITIES AUTHORIZED UNDER THE LICENSE ISSUED UNDER RULE 3701:1-46-13 OF THIS CHAPTER.

- (D) THE REPORT MUST COVER THE PERIOD BETWEEN THE FILING OF THE PRECEDING REPORT AND THE OCCURRENCE SPECIFIED IN PARAGRAPHS (C)

(1), (2), OR (3) OF THIS RULE. IF NO TRANSFERS OF BYPRODUCT, ACCELERATOR PRODUCED MATERIALS, OR RADIUM HAVE BEEN MADE UNDER RULE 3701:1-46-13 OF THIS CHAPTER DURING THE REPORTING PERIOD, THE REPORT SHALL SO INDICATE.

- (E) THE LICENSEE SHALL MAINTAIN THE RECORD OF A TRANSFER FOR A PERIOD OF ONE YEAR AFTER THE EVENT IS INCLUDED IN A REPORT TO THE DIRECTOR.

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Public Health Council

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3701:1-46-15 INTRODUCTION OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN EXEMPT CONCENTRATIONS INTO PRODUCTS OR MATERIALS, AND TRANSFER OF OWNERSHIP OR POSSESSION OF ACCELERATOR PRODUCED MATERIAL OR RADIUM IN EXEMPT CONCENTRATIONS: PROHIBITION OF INTRODUCTION.

NO PERSON MAY INTRODUCE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM INTO A PRODUCT OR MATERIAL KNOWING OR HAVING REASON TO BELIEVE THAT IT WILL BE TRANSFERRED TO PERSONS EXEMPT UNDER RULE 3701:1-40-08 OF THE ADMINISTRATIVE CODE OR EQUIVALENT REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION, AN AGREEMENT STATE, OR A NARM LICENSING STATE EXCEPT IN ACCORDANCE WITH A LICENSE ISSUED PURSUANT TO RULE 3701:1-46-13 OF THIS CHAPTER OR THE GENERAL LICENSE PROVIDED IN RULE 3701:1-40-28 OF THE ADMINISTRATIVE CODE.

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3701:1-46-16 CERTAIN ITEMS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL OR RADIUM; REQUIREMENTS FOR LICENSE TO APPLY

AN APPLICATION FOR A SPECIFIC LICENSE TO APPLY BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM TO OR TO INCORPORATE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM INTO THE PRODUCTS SPECIFIED IN CHAPTER 3701:1-40-09 OF THE ADMINISTRATIVE CODE WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
- (B) THE APPLICANT SUBMITS SUFFICIENT INFORMATION REGARDING THE PRODUCT PERTINENT TO EVALUATION OF THE POTENTIAL RADIATION EXPOSURE, INCLUDING:
 - (1) CHEMICAL AND PHYSICAL FORM AND MAXIMUM QUANTITY OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN EACH PRODUCT;
 - (2) DETAILS OF CONSTRUCTION AND DESIGN OF EACH PRODUCT;
 - (3) THE METHOD OF CONTAINMENT OR BINDING OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN THE PRODUCT;
 - (4) PROCEDURES FOR AND RESULTS OF PROTOTYPE TESTING TO DEMONSTRATE THAT THE MATERIAL WILL NOT BECOME DETACHED FROM THE PRODUCT AND THAT THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM WILL NOT BE RELEASED TO THE ENVIRONMENT UNDER THE MOST SEVERE CONDITIONS LIKELY TO BE ENCOUNTERED IN NORMAL USE OF THE PRODUCT;
 - (5) QUALITY CONTROL PROCEDURES TO BE FOLLOWED IN THE FABRICATION OF PRODUCTION LOTS OF THE PRODUCT AND THE QUALITY CONTROL STANDARDS THE PRODUCT WILL BE REQUIRED TO MEET;
 - (6) THE PROPOSED METHOD OF LABELING OR MARKING EACH UNIT, EXCEPT TIMEPIECES OR HANDS OR DIALS CONTAINING TRITIUM OR PROMETHIUM-147, AND ITS CONTAINER WITH THE IDENTIFICATION OF THE MANUFACTURER OR INITIAL TRANSFEROR OF THE PRODUCT AND THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN THE PRODUCT;
 - (7) FOR PRODUCTS FOR WHICH LIMITS ON LEVELS OF RADIATION ARE SPECIFIED IN RULE 3701:1-40-09 OF THE ADMINISTRATIVE CODE, THE RADIATION LEVEL AND THE METHOD OF MEASUREMENT;
 - (8) ANY ADDITIONAL INFORMATION, INCLUDING EXPERIMENTAL STUDIES AND TESTS, REQUIRED BY THE DIRECTOR TO FACILITATE A DETERMINATION OF THE SAFETY OF THE PRODUCT.

- (C) EACH PRODUCT WILL CONTAIN NO MORE THAN THE QUANTITY OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM SPECIFIED FOR THAT PRODUCT IN RULE 3701:1-40-09 OF THE ADMINISTRATIVE CODE. THE LEVELS OF RADIATION FROM EACH PRODUCT CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM WILL NOT EXCEED THE LIMITS SPECIFIED FOR THAT PRODUCT IN RULE 3701:1-40-09 OF THE ADMINISTRATIVE CODE.
- (D) THE DIRECTOR DETERMINES THAT:
- (1) THE METHOD OF CONTAINMENT OR BINDING OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN THE PRODUCT IS SUCH THAT THE RADIOACTIVE MATERIAL WILL NOT BE RELEASED OR BE REMOVED FROM THE PRODUCT UNDER THE MOST SEVERE CONDITIONS WHICH ARE LIKELY TO BE ENCOUNTERED IN NORMAL USE AND HANDLING. TRITIUM WILL BE CONSIDERED TO BE PROPERLY BOUND TO DIALS, HANDS, AND POINTERS IF THERE IS NO VISIBLE FLAKING OR CHIPPING AND THE TOTAL LOSS OF TRITIUM DOES NOT EXCEED FIVE PERCENT OF THE TOTAL TRITIUM WHEN PROTOTYPE DIALS, HANDS, AND POINTERS ARE SUBJECTED TO THE FOLLOWING TESTS IN THE ORDER SPECIFIED BELOW.
 - (a) ATTACHMENT OF DIALS TO A VIBRATING FIXTURE AND VIBRATION AT A RATE OF NOT LESS THAN TWENTY SIX CYCLES PER SECOND AND A VIBRATION ACCELERATION OF NOT LESS THAN TWO G FOR A PERIOD OF NOT LESS THAN ONE HOUR; AND
 - (b) ATTACHMENT OF THE HUB ENDS OF THE HANDS OR POINTERS TO A CLAMP AND BENDING OF HANDS OR POINTERS OVER A ONE-INCH DIAMETER CYLINDER; AND
 - (c) TOTAL IMMERSION OF THE DIALS, HANDS AND POINTERS USED IN THE TESTS DESCRIBED IN PARAGRAPHS (D)(1)(a) AND (b) OF THIS RULE IN ONE HUNDRED MILLILITERS OF WATER AT ROOM TEMPERATURE FOR A PERIOD OF TWENTY FOUR CONSECUTIVE HOURS AND ANALYSIS OF THE TEST WATER FOR ITS RADIOACTIVE MATERIAL CONTENT BY LIQUID SCINTILLATION COUNTING OR OTHER EQUALLY SENSITIVE METHOD.
 - (2) THE PRODUCT HAS BEEN SUBJECTED TO AND MEETS THE REQUIREMENTS OF THE PROTOTYPE TESTS. PROTOTYPE TESTS FOR AUTOMOBILE LOCK ILLUMINATORS ARE PRESCRIBED BY RULE 3701:1-46-29 OF THE ADMINISTRATIVE CODE.

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Jodi Govern, Secretary
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Date

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3701:1-46-17 CERTAIN ITEMS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM; QUALITY ASSURANCE, PROHIBITION OF TRANSFER, AND LABELING.

- (A) EACH PERSON LICENSED UNDER RULE 3701:1-46-16 OF THIS CHAPTER SHALL:
- (1) MAINTAIN QUALITY ASSURANCE PRACTICES IN THE MANUFACTURE OF THE PART OR PRODUCT, OR THE INSTALLATION OF THE PART INTO THE PRODUCT;
 - (2) SUBJECT INSPECTION LOTS TO SUCH TESTING AS MAY BE REQUIRED AS A CONDITION OF THE LICENSE ISSUED UNDER RULE 3701:1-46-16 OF THIS CHAPTER TAKING A RANDOM SAMPLE OF THE SIZE REQUIRED BY THE TABLES IN RULE 3701:1-46-48 OF THIS CHAPTER, AND FOR LOT TOLERANCE PERCENT DEFECTIVE OF FIVE PERCENT, ACCEPT OR REJECT INSPECTION LOTS IN ACCORDANCE WITH THE DIRECTIONS OF RULE 3701:1-46-48 OF THIS CHAPTER; AND
 - (3) VISUALLY INSPECT EACH UNIT, EXCEPT ELECTRON TUBES CONTAINING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL, IN INSPECTION LOTS. ANY UNIT WHICH HAS AN OBSERVABLE PHYSICAL DEFECT THAT COULD AFFECT CONTAINMENT OF THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL SHALL BE CONSIDERED AS A DEFECTIVE UNIT.
- (B) AN APPLICATION FOR A LICENSE OR FOR AMENDMENT OF A LICENSE MAY INCLUDE A DESCRIPTION OF PROCEDURES PROPOSED AS ALTERNATIVES TO THOSE PRESCRIBED BY PARAGRAPH (A)(2) OF THIS RULE, AND PROPOSED CRITERIA FOR ACCEPTANCE UNDER THOSE PROCEDURES. THE DIRECTOR WILL APPROVE THE PROPOSED ALTERNATIVE PROCEDURES IF THE APPLICANT DEMONSTRATES THAT THE OPERATING CHARACTERISTIC CURVE OR CONFIDENCE INTERVAL ESTIMATE FOR THE ALTERNATIVE PROCEDURES PROVIDES A LOT TOLERANCE PERCENT DEFECTIVE OF FIVE PERCENT AT THE CONSUMER'S RISK OF 0.10.
- (C) NO PERSON LICENSED UNDER RULE 3701:1-46-16 OF THIS CHAPTER SHALL TRANSFER TO OTHER PERSONS FOR USE UNDER RULE 3701:1-40-09 OF THE ADMINISTRATIVE CODE, OR EQUIVALENT REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE:
- (1) ANY PART OR PRODUCT WHICH HAS BEEN TESTED AND FOUND DEFECTIVE UNDER THE CRITERIA AND PROCEDURES SPECIFIED IN THE LICENSE ISSUED UNDER RULE 3701:1-46-16 OF THIS CHAPTER, UNLESS THE DEFECTIVE UNITS HAVE BEEN REPAIRED OR REWORKED AND HAVE THEN MET SUCH CRITERIA AS MAY BE REQUIRED AS A CONDITION OF THE LICENSE ISSUED UNDER RULE 3701:1-46-16 OF THIS CHAPTER; OR

- (2) ANY INSPECTION LOT WHICH HAS BEEN REJECTED AS A RESULT OF THE PROCEDURES IN RULE 3701:1-46-48 OF THIS CHAPTER OR ALTERNATIVE PROCEDURES IN PARAGRAPH (B) OF THIS RULE, UNLESS THE DEFECTIVE UNITS HAVE BEEN SORTED AND REMOVED OR HAVE BEEN REPAIRED OR REWORKED AND HAVE THEN MET SUCH CRITERIA AS MAY BE REQUIRED AS A CONDITION OF THE LICENSE ISSUED UNDER RULE 3701:1-46-16 OF THE CHAPTER.

- (D) EACH PERSON LICENSED UNDER RULE 3701:1-46-16 OF THE ADMINISTRATIVE CODE SHALL LABEL OR MARK EACH UNIT, EXCEPT TIMEPIECES OR HANDS OR DIALS CONTAINING TRITIUM OR PROMETHIUM-147, AND ITS CONTAINER SO THAT THE MANUFACTURER OR INITIAL TRANSFEROR OF THE PRODUCT AND THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN THE PRODUCT CAN BE IDENTIFIED.

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3701:1-46-18 CERTAIN ITEMS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM: RECORDS AND REPORTS OF TRANSFER.

- (A) EACH PERSON LICENSED UNDER RULE 3701:1-46-16 OR RULE 3701:1-46-19 OF THIS CHAPTER SHALL MAINTAIN RECORDS OF TRANSFER OF MATERIAL AND SUBMIT A REPORT TO THE DIRECTOR.
- (B) THE REPORT MUST INCLUDE THE FOLLOWING INFORMATION ON ITEMS TRANSFERRED TO OTHER PERSONS FOR USE UNDER RULES 3701:1-40-09 OR 3701:1-40-19 OF THE ADMINISTRATIVE CODE, OR EQUIVALENT REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE:
 - (1) A DESCRIPTION OR IDENTIFICATION OF THE TYPE OF EACH PRODUCT;
 - (2) FOR EACH RADIONUCLIDE IN EACH TYPE OF PRODUCT, THE TOTAL QUANTITY OF THE RADIONUCLIDE; AND
 - (3) THE NUMBER OF UNITS OF EACH TYPE OF PRODUCT TRANSFERRED DURING THE REPORTING PERIOD.
- (C) THE LICENSEE SHALL FILE THE REPORT WITHIN THIRTY DAYS AFTER:
 - (1) FIVE YEARS AFTER FILING THE PRECEDING REPORT; OR
 - (2) FILING AN APPLICATION FOR RENEWAL OF THE LICENSE UNDER RULE 3701-38-02.1 OF THE ADMINISTRATIVE CODE; OR
 - (3) NOTIFYING THE DIRECTOR UNDER RULE 3701:1-40-16 OF THE ADMINISTRATIVE CODE, OF THE LICENSEE'S DECISION TO PERMANENTLY DISCONTINUE ACTIVITIES AUTHORIZED UNDER THE LICENSE ISSUED UNDER RULES 3701:1-46-16 OR 3701:1-46-19 OF THIS CHAPTER.
- (D) THE REPORT MUST COVER THE PERIOD BETWEEN THE FILING OF THE PRECEDING REPORT AND THE OCCURANCE SPECIFIED IN PARAGRAPHS (C) (1), (2), OR (3) OF THIS RULE. IF NO TRANSFERS OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM HAVE BEEN MADE UNDER RULES 3701:1-46-16 OR 3701:1-46-19 OF THIS CHAPTER DURING THE REPORTING PERIOD, THE REPORT MUST SO INDICATE.
- (E) THE LICENSEE SHALL MAINTAIN THE RECORD OF A TRANSFER FOR A PERIOD OF ONE YEAR AFTER THE EVENT IS INCLUDED IN A REPORT TO THE DIRECTOR.

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R.C. 119.032 review date:

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3701:1-46-19 RESINS CONTAINING SCANDIUM-46 AND DESIGNED FOR SAND-CONSOLIDATION IN OIL WELLS: REQUIREMENTS FOR LICENSE TO MANUFACTURE, OR INITIALLY TRANSFER FOR SALE OR DISTRIBUTION.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, OR INITIALLY TRANSFER FOR SALE OR DISTRIBUTION, SYNTHETIC PLASTIC RESINS CONTAINING SCANDIUM-46 FOR USE PURSUANT TO RULE 3701:1-40-10 OF THE ADMINISTRATIVE CODE WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
- (B) THE PRODUCT IS DESIGNED TO BE USED ONLY FOR SAND-CONSOLIDATION IN OIL WELLS;
- (C) THE APPLICANT SUBMITS THE FOLLOWING INFORMATION:
 - (1) THE GENERAL DESCRIPTION OF THE PRODUCT TO BE MANUFACTURED OR INITIALLY TRANSFERRED.
 - (2) A DESCRIPTION OF CONTROL PROCEDURES TO BE USED TO ASSURE THAT THE CONCENTRATION OF SCANDIUM-46 IN THE FINAL PRODUCT AT THE TIME OF DISTRIBUTION WILL NOT EXCEED 51.8 MEGABECQUERELS / MILLILITER (ONE THOUSAND FOUR HUNDRED MICROCURIE / MILLILITER).
- (D) EACH CONTAINER OF SUCH PRODUCT WILL BEAR A DURABLE, LEGIBLE LABEL APPROVED BY THE DIRECTOR, WHICH CONTAINS THE FOLLOWING INFORMATION:
 - (1) THE PRODUCT NAME;
 - (2) A STATEMENT THAT THE PRODUCT CONTAINS RADIOACTIVE SCANDIUM AND IS DESIGNED AND MANUFACTURED ONLY FOR SAND-CONSOLIDATION IN OIL WELLS;
 - (3) INSTRUCTIONS NECESSARY FOR PROPER USE; AND
 - (4) THE MANUFACTURER'S NAME.

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3701:1-46-20 MANUFACTURE OF EXEMPT QUANTITIES OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM: REQUIREMENTS FOR LICENSE.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, PROCESS, OR PRODUCE QUANTITIES OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM FOR COMMERCIAL DISTRIBUTION TO PERSONS EXEMPT PURSUANT TO RULE 3701:1-40-11 OF THE ADMINISTRATIVE CODE OR THE EQUIVALENT REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE, PROVIDED, HOWEVER, THAT THE REQUIREMENTS OF PARAGRAPHS (A)(2) AND (A)(3) OF RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE DO NOT APPLY TO AN APPLICATION FOR A LICENSE TO TRANSFER BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM MANUFACTURED, PROCESSED, PRODUCED, PACKAGED, OR REPACKAGED PURSUANT TO A LICENSE ISSUED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE;
- (B) THE BYPRODUCT AND ACCELERATOR PRODUCED MATERIAL IS NOT CONTAINED IN ANY FOOD, BEVERAGE, COSMETIC, DRUG, OR OTHER COMMODITY DESIGNED FOR INGESTION OR INHALATION BY, OR APPLICATION TO, A HUMAN BEING;
- (C) THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IS IN THE FORM OF PROCESSED CHEMICAL ELEMENTS, COMPOUNDS, OR MIXTURES, TISSUE SAMPLES, BIOASSAY SAMPLES, COUNTING STANDARDS, PLATED OR ENCAPSULATED SOURCES, OR SIMILAR SUBSTANCES, IDENTIFIED AS RADIOACTIVE AND TO BE USED FOR ITS RADIOACTIVE PROPERTIES, BUT IS NOT INCORPORATED INTO ANY MANUFACTURED OR ASSEMBLED COMMODITY, PRODUCT, OR DEVICE INTENDED FOR COMMERCIAL DISTRIBUTION; AND
- (D) THE APPLICANT SUBMITS COPIES OF PROTOTYPE LABELS AND BROCHURES AND THE DIRECTOR APPROVES SUCH LABELS AND BROCHURES.
- (E) DISTRIBUTION OF EXEMPT QUANTITIES OF BYPRODUCT MATERIAL SHALL SATISFY THE CRITERIA IN PARAGRAPH (D) OF RULE 3701:1-40-08 OF THE ADMINISTRATIVE CODE.

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3701:1-46-21 MANUFACTURE OF EXEMPT QUANTITIES OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM: CONDITIONS OF LICENSES.

EACH LICENSE ISSUED UNDER RULE 3701:1-46-20 OF THIS CHAPTER IS SUBJECT TO THE FOLLOWING CONDITIONS:

- (A) NO MORE THAN TEN EXEMPT QUANTITIES OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM SET FORTH IN RULE 3701:1-40-11 OF THE ADMINISTRATIVE CODE, SHALL BE SOLD OR TRANSFERRED IN ANY SINGLE TRANSACTION. FOR PURPOSES OF THIS REQUIREMENT, AN INDIVIDUAL EXEMPT QUANTITY MAY BE COMPOSED OF FRACTIONAL PARTS OF ONE OR MORE OF THE EXEMPT QUANTITIES IN RULE 3701:1-40-11 OF THE ADMINISTRATIVE CODE, PROVIDED THAT THE SUM OF SUCH FRACTIONS SHALL NOT EXCEED UNITY.
- (B) EACH QUANTITY OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM SET FORTH IN RULE 3701:1-40-11 OF THE ADMINISTRATIVE CODE SHALL BE SEPARATELY AND INDIVIDUALLY PACKAGED. NO MORE THAN TEN SUCH PACKAGED EXEMPT QUANTITIES SHALL BE CONTAINED IN ANY OUTER PACKAGE FOR TRANSFER TO PERSONS EXEMPT PURSUANT TO RULE 3701:1-40-11 OF THE ADMINISTRATIVE CODE. THE OUTER PACKAGE SHALL BE SUCH THAT THE DOSE RATE AT THE EXTERNAL SURFACE OF THE PACKAGE DOES NOT EXCEED FIVE MICROSIEVERTS (0.5 MILLIREM) PER HOUR.
- (C) THE IMMEDIATE CONTAINER OF EACH QUANTITY OR SEPARATELY PACKAGED FRACTIONAL QUANTITY OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM SHALL BEAR A DURABLE, LEGIBLE LABEL WHICH
 - (1) IDENTIFIES THE RADIONUCLIDE AND THE QUANTITY OF RADIOACTIVITY, AND
 - (2) BEARS THE WORDS "RADIOACTIVE MATERIAL."
- (D) IN ADDITION TO THE LABELING INFORMATION REQUIRED BY PARAGRAPH (C) OF THIS RULE, THE LABEL AFFIXED TO THE IMMEDIATE CONTAINER, OR AN ACCOMPANYING BROCHURE, SHALL ALSO
 - (1) STATE THAT THE CONTENTS ARE EXEMPT FROM OHIO, NRC OR AGREEMENT STATE OR NARM LICENSING STATE LICENSING REQUIREMENTS;
 - (2) BEAR THE WORDS "RADIOACTIVE MATERIAL-NOT FOR HUMAN USE-INTRODUCTION INTO FOODS, BEVERAGES, COSMETICS, DRUGS, OR MEDICINALS, OR INTO PRODUCTS MANUFACTURED FOR COMMERCIAL DISTRIBUTION IS PROHIBITED-EXEMPT QUANTITIES SHOULD NOT BE COMBINED"; AND
 - (3) SET FORTH APPROPRIATE ADDITIONAL RADIATION SAFETY PRECAUTIONS AND INSTRUCTIONS RELATING TO THE HANDLING, USE, STORAGE, AND DISPOSAL OF THE RADIOACTIVE MATERIAL.

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3701:1-46-22 MANUFACTURE OF EXEMPT QUANTITIES OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM: RECORDS AND MATERIAL TRANSFER REPORTS.

- (A) EACH PERSON LICENSED UNDER RULE 3701:1-46-20 OF THIS CHAPTER SHALL MAINTAIN RECORDS OF TRANSFER OF MATERIAL IDENTIFYING, BY NAME AND ADDRESS, EACH PERSON TO WHOM BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IS TRANSFERRED FOR USE UNDER RULE 3701:1-40-11 OF THE ADMINISTRATIVE CODE OR THE EQUIVALENT REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE AND STATING THE KINDS AND QUANTITIES OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM TRANSFERRED. THE LICENSEE SHALL MAINTAIN THE RECORD OF A TRANSFER FOR A PERIOD OF ONE YEAR AFTER THE EVENT IS INCLUDED IN A SUMMARY REPORT TO THE DIRECTOR.
- (B) THE LICENSEE SHALL FILE A SUMMARY REPORT STATING THE TOTAL QUANTITY OF EACH RADIONUCLIDE TRANSFERRED UNDER THE SPECIFIC LICENSE WITH THE DIRECTOR.
- (C) THE LICENSEE SHALL FILE THE SUMMARY REPORT WITHIN THIRTY DAYS FOLLOWING:
 - (1) FIVE YEARS AFTER FILING THE PRECEDING REPORT; OR
 - (2) FILING AN APPLICATION FOR RENEWAL OF THE LICENSE UNDER RULE 3701-38-02.1 OF THE ADMINISTRATIVE CODE; OR
 - (3) NOTIFYING THE DIRECTOR UNDER RULE 3701:1-40-16 OF THE ADMINISTRATIVE CODE, OF THE LICENSEE'S DECISION TO PERMANENTLY DISCONTINUE ACTIVITIES AUTHORIZED UNDER THE LICENSE ISSUED UNDER RULE 3701:1-46-20 OF THIS CHAPTER.
- (D) THE REPORT MUST COVER THE PERIOD BETWEEN THE FILING OF THE PRECEDING REPORT AND THE OCCURRENCES SPECIFIED IN PARAGRAPH (C)(1), (2), OR (3) OF THIS RULE. IF NO TRANSFERS OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM HAVE BEEN MADE UNDER RULE 3701:1-46-20 OF THIS CHAPTER DURING THE REPORTING PERIOD, THE REPORT MUST SO INDICATE.

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3701:1-46-23 RADIOACTIVE DRUG: MANUFACTURE, PREPARATION OF CAPSULES CONTAINING CARBON-14 UREA EACH FOR IN-VIVO DIAGNOSTIC USE FOR HUMANS TO PERSONS EXEMPT FROM LICENSING; REQUIREMENTS FOR A LICENSE.

- (A) AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, PREPARE, PROCESS, OR PRODUCE CAPSULES CONTAINING THIRTY SEVEN KBQ (ONE MICROCURIE) CARBON-14 UREA (ALLOWING FOR NOMINAL VARIATION THAT MAY OCCUR DURING THE MANUFACTURING PROCESS) EACH FOR IN-VIVO DIAGNOSTIC USE, TO PERSONS EXEMPT FROM LICENSING UNDER RULE 3701:1-40-03 OF THE ADMINISTRATIVE CODE OR THE EQUIVALENT REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE WILL BE APPROVED IF:
- (1) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE, PROVIDED THAT THE REQUIREMENTS OF PARAGRAPHS (A)(2) AND (A)(3) OF RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE DO NOT APPLY TO AN APPLICATION FOR A LICENSE TO TRANSFER BYPRODUCT MATERIAL MANUFACTURED, PREPARED, PROCESSED, PRODUCED, PACKAGED, OR REPACKAGED PURSUANT TO A LICENSE ISSUED BY AN AGREEMENT STATE;
 - (2) THE APPLICANT MEETS THE REQUIREMENTS UNDER PARAGRAPH (A)(2) OF RULE 3701:1-46-43;
 - (3) THE APPLICANT PROVIDES EVIDENCE THAT EACH CAPSULE CONTAINS THIRTY SEVEN KBQ (ONE MICROCURIE) CARBON-14 UREA (ALLOWING FOR NOMINAL VARIATION THAT MAY OCCUR DURING THE MANUFACTURING PROCESS);
 - (4) THE CARBON-14 UREA IS NOT CONTAINED IN ANY FOOD, BEVERAGE, COSMETIC, DRUG (EXCEPT AS DESCRIBED IN THIS RULE) OR OTHER COMMODITY DESIGNED FOR INGESTION OR INHALATION BY, OR TOPICAL APPLICATION TO A HUMAN BEING;
 - (5) THE CARBON-14 UREA IS IN THE FORM OF A CAPSULE, IDENTIFIED AS RADIOACTIVE, AND TO BE USED FOR ITS RADIOACTIVE PROPERTIES, BUT IS NOT INCORPORATED INTO ANY MANUFACTURED OR ASSEMBLED COMMODITY, PRODUCT, OR DEVICE INTENDED FOR COMMERCIAL DISTRIBUTION; AND
 - (6) THE APPLICANT SUBMITS COPIES OF PROTOTYPE LABELS AND BROCHURES AND THE UNITED STATES NUCLEAR REGULATORY COMMISSION APPROVES THESE LABELS AND BROCHURES.
- (B) NOTHING IN THIS RULE RELIEVES THE LICENSEE FROM COMPLYING WITH APPLICABLE FDA, OTHER FEDERAL, AND STATE REQUIREMENTS GOVERNING DRUGS.

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3701:1-46-24 RADIOACTIVE DRUG: MANUFACTURE, PREPARATION OF CAPSULES CONTAINING CARBON-14 UREA EACH FOR IN-VIVO DIAGNOSTIC USE FOR HUMANS TO PERSONS EXEMPT FROM LICENSING: CONDITIONS OF LICENSE.

EACH LICENSE ISSUED UNDER RULE 3701:1-46-23 OF THIS CHAPTER IS SUBJECT TO THE FOLLOWING CONDITIONS:

- (A) THE IMMEDIATE CONTAINER OF THE CAPSULE(S) MUST BEAR A DURABLE, LEGIBLE LABEL WHICH:
- (1) IDENTIFIES THE RADIOISOTOPE, THE PHYSICAL AND CHEMICAL FORM, THE QUANTITY OF RADIOACTIVITY OF EACH CAPSULE AT A SPECIFIC DATE; AND
 - (2) BEARS THE WORDS "RADIOACTIVE MATERIAL."
- (B) IN ADDITION TO THE LABELING INFORMATION REQUIRED BY PARAGRAPH (A) OF THIS RULE, THE LABEL AFFIXED TO THE IMMEDIATE CONTAINER, OR AN ACCOMPANYING BROCHURE ALSO MUST:
- (1) STATE THAT THE CONTENTS ARE EXEMPT FROM OHIO, NUCLEAR REGULATORY COMMISSION OR AGREEMENT STATE LICENSING REQUIREMENTS; AND
 - (2) BEAR THE WORDS "RADIOACTIVE MATERIAL. FOR IN-VIVO DIAGNOSTIC USE ONLY. THIS MATERIAL IS NOT TO BE USED FOR RESEARCH INVOLVING HUMAN SUBJECTS AND MUST NOT BE INTRODUCED INTO FOODS, BEVERAGES, COSMETICS, OR OTHER DRUGS OR MEDICINALS, OR INTO PRODUCTS MANUFACTURED FOR COMMERCIAL DISTRIBUTION. THIS MATERIAL MAY BE DISPOSED OF IN ORDINARY TRASH."

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3701:1-46-25 SELF-LUMINOUS PRODUCTS CONTAINING TRITIUM, KRYPTON-85 OR PROMETHIUM-147: REQUIREMENTS FOR LICENSE TO MANUFACTURE, PROCESS, PRODUCE.

- (A) AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, PROCESS, OR PRODUCE SELF-LUMINOUS PRODUCTS CONTAINING TRITIUM, KRYPTON-85, OR PROMETHIUM-147, OR TO INITIALLY TRANSFER SUCH PRODUCTS FOR USE PURSUANT TO RULE 3701:1-40-12 OF THE ADMINISTRATIVE CODE OR EQUIVALENT REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE, WILL BE APPROVED IF:
- (1) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE: PROVIDED, HOWEVER, THAT THE REQUIREMENTS OF PARAGRAPHS (A)(2) AND (A)(3) OF RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE, DO NOT APPLY TO AN APPLICATION FOR A LICENSE TO TRANSFER TRITIUM, KRYPTON-85, OR PROMETHIUM-147 IN SELF-LUMINOUS PRODUCTS MANUFACTURED, PROCESSED, OR PRODUCED PURSUANT TO A LICENSE ISSUED BY AN AGREEMENT STATE.
 - (2) THE APPLICANT SUBMITS SUFFICIENT INFORMATION RELATING TO THE DESIGN, MANUFACTURE, PROTOTYPE TESTING, QUALITY CONTROL PROCEDURES, LABELING OR MARKING, AND CONDITIONS OF HANDLING, STORAGE, USE, AND DISPOSAL OF THE SELF-LUMINOUS PRODUCT TO DEMONSTRATE THAT THE PRODUCT WILL MEET THE SAFETY CRITERIA SET FORTH IN RULE 3701:1-46-26 OF THIS CHAPTER. THE INFORMATION SHOULD INCLUDE:
 - (a) A DESCRIPTION OF THE PRODUCT AND ITS INTENDED USE OR USES.
 - (b) THE TYPE AND QUANTITY OF BYPRODUCT MATERIAL IN EACH UNIT.
 - (c) CHEMICAL AND PHYSICAL FORM OF THE BYPRODUCT MATERIAL IN THE PRODUCT AND CHANGES IN CHEMICAL AND PHYSICAL FORM THAT MAY OCCUR DURING THE USEFUL LIFE OF THE PRODUCT.
 - (d) SOLUBILITY IN WATER AND BODY FLUIDS OF THE FORMS OF THE BYPRODUCT MATERIAL IDENTIFIED IN PARAGRAPHS (A)(2) (c) AND (I) OF THIS RULE.
 - (e) DETAILS OF CONSTRUCTION AND DESIGN OF THE PRODUCT AS RELATED TO CONTAINMENT AND SHIELDING OF THE BYPRODUCT MATERIAL AND OTHER SAFETY FEATURES UNDER NORMAL AND SEVERE CONDITIONS OF HANDLING, STORAGE, USE, AND DISPOSAL OF THE PRODUCT.

- (f) MAXIMUM EXTERNAL RADIATION LEVELS AT FIVE AND TWENTY-FIVE CENTIMETERS FROM ANY EXTERNAL SURFACE OF THE PRODUCT, AVERAGED OVER AN AREA NOT TO EXCEED TEN SQUARE CENTIMETERS, AND THE METHOD OF MEASUREMENT.
- (g) DEGREE OF ACCESS OF HUMAN BEINGS TO THE PRODUCT DURING NORMAL HANDLING AND USE.
- (h) TOTAL QUANTITY OF BYPRODUCT MATERIAL EXPECTED TO BE DISTRIBUTED IN THE PRODUCT ANNUALLY.
- (i) THE EXPECTED USEFUL LIFE OF THE PRODUCT.
- (j) THE PROPOSED METHOD OF LABELING OR MARKING EACH UNIT WITH IDENTIFICATION OF THE MANUFACTURER OR INITIAL TRANSFEROR OF THE PRODUCT AND THE BYPRODUCT MATERIAL IN THE PRODUCT.
- (k) PROCEDURES FOR PROTOTYPE TESTING OF THE PRODUCT TO DEMONSTRATE THE EFFECTIVENESS OF THE CONTAINMENT, SHIELDING, AND OTHER SAFETY FEATURES UNDER BOTH NORMAL AND SEVERE CONDITIONS OF HANDLING, STORAGE, USE, AND DISPOSAL OF THE PRODUCT.
- (l) RESULTS OF THE PROTOTYPE TESTING OF THE PRODUCT, INCLUDING ANY CHANGE IN THE FORM OF THE BYPRODUCT MATERIAL CONTAINED IN THE PRODUCT, THE EXTENT TO WHICH THE BYPRODUCT MATERIAL MAY BE RELEASED TO THE ENVIRONMENT, ANY INCREASE IN EXTERNAL RADIATION LEVELS, AND ANY OTHER CHANGES IN SAFETY FEATURES.
- (m) THE ESTIMATED EXTERNAL RADIATION DOSES AND DOSE COMMITMENTS RELEVANT TO THE SAFETY CRITERIA IN RULE 3701:1-46-26 OF THIS CHAPTER AND THE BASIS FOR SUCH ESTIMATES.
- (n) A DETERMINATION THAT THE PROBABILITIES WITH RESPECT TO THE DOSES REFERRED TO IN PARAGRAPH (D) OF RULE 3701:1-46-26 OF THIS CHAPTER MEET THE CRITERIA OF THAT PARAGRAPH.
- (o) QUALITY CONTROL PROCEDURES TO BE FOLLOWED IN THE FABRICATION OF PRODUCTION LOTS OF THE PRODUCT AND THE QUALITY CONTROL STANDARDS THE PRODUCT WILL BE REQUIRED TO MEET.
- (p) ANY ADDITIONAL INFORMATION, INCLUDING EXPERIMENTAL STUDIES AND TESTS, REQUIRED BY THE DIRECTOR.

- (B) NOTWITHSTANDING THE PROVISIONS OF PARAGRAPH (A) OF THIS RULE, THE DIRECTOR MAY DENY AN APPLICATION FOR A SPECIFIC LICENSE UNDER THIS SECTION IF THE END USES OF THE PRODUCT CANNOT BE REASONABLY FORESEEN.

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3701:1-46-26 SELF-LUMINOUS PRODUCTS CONTAINING TRITIUM, KRYPTON-85 OR PROMETHIUM-147: SAFETY CRITERIA.

AN APPLICANT FOR A LICENSE UNDER RULE 3701:1-46-25 OF THIS CHAPTER SHALL DEMONSTRATE THAT THE PRODUCT IS DESIGNED AND WILL BE MANUFACTURED SO THAT:

- (A) IN NORMAL USE AND DISPOSAL OF A SINGLE EXEMPT UNIT, IT IS UNLIKELY THAT THE EXTERNAL RADIATION DOSE IN ANY ONE YEAR, OR THE DOSE COMMITMENT RESULTING FROM THE INTAKE OF RADIOACTIVE MATERIAL IN ANY ONE YEAR, TO A SUITABLE SAMPLE OF THE GROUP OF INDIVIDUALS EXPECTED TO BE MOST HIGHLY EXPOSED TO RADIATION OR RADIOACTIVE MATERIAL FROM THE PRODUCT WILL EXCEED THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN I OF THE TABLE IN APPENDIX A TO THIS RULE.
- (B) IN NORMAL HANDLING AND STORAGE OF THE QUANTITIES OF EXEMPT UNITS LIKELY TO ACCUMULATE IN ONE LOCATION DURING MARKETING, DISTRIBUTION, INSTALLATION, AND SERVICING OF THE PRODUCT, IT IS UNLIKELY THAT THE EXTERNAL RADIATION DOSE IN ANY ONE YEAR, OR THE DOSE COMMITMENT RESULTING FROM THE INTAKE OF RADIOACTIVE MATERIAL IN ANY ONE YEAR, TO A SUITABLE SAMPLE OF THE GROUP OF INDIVIDUALS EXPECTED TO BE MOST HIGHLY EXPOSED TO RADIATION OR RADIOACTIVE MATERIAL FROM THE PRODUCT WILL EXCEED THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN II OF THE TABLE IN APPENDIX A TO THIS RULE.
- (C) IT IS UNLIKELY THAT THERE WILL BE A SIGNIFICANT REDUCTION IN THE EFFECTIVENESS OF THE CONTAINMENT, SHIELDING, OR OTHER SAFETY FEATURES OF THE PRODUCT FROM WEAR AND ABUSE LIKELY TO OCCUR IN NORMAL HANDLING AND USE OF THE PRODUCT DURING ITS USEFUL LIFE.
- (D) IN USE AND DISPOSAL OF A SINGLE EXEMPT UNIT, OR IN HANDLING AND STORAGE OF THE QUANTITIES OF EXEMPT UNITS LIKELY TO ACCUMULATE IN ONE LOCATION DURING MARKETING, DISTRIBUTION, INSTALLATION, AND SERVICING OF THE PRODUCT, THE PROBABILITY IS LOW THAT THE CONTAINMENT, SHIELDING, OR OTHER SAFETY FEATURES OF THE PRODUCT WOULD FAIL UNDER SUCH CIRCUMSTANCES THAT A PERSON WOULD RECEIVE AN EXTERNAL RADIATION DOSE OR DOSE COMMITMENT IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN III OF THE TABLE IN APPENDIX A TO THIS RULE, AND THE PROBABILITY IS NEGLIGIBLE THAT A PERSON WOULD RECEIVE AN EXTERNAL RADIATION DOSE OR DOSE COMMITMENT IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN IV OF THE TABLE IN APPENDIX A TO THIS RULE.

IT IS THE INTENT OF THIS PARAGRAPH THAT AS THE MAGNITUDE OF THE POTENTIAL DOSE INCREASES ABOVE THAT PERMITTED UNDER NORMAL CONDITIONS, THE PROBABILITY THAT ANY INDIVIDUAL WILL RECEIVE SUCH A DOSE MUST DECREASE.

THE PROBABILITIES HAVE BEEN EXPRESSED IN GENERAL TERMS TO EMPHASIZE THE APPROXIMATE NATURE OF THE ESTIMATES WHICH ARE TO BE MADE. THE FOLLOWING VALUES MAY BE USED AS GUIDES IN ESTIMATING COMPLIANCE WITH THE CRITERIA: LOW-NOT MORE THAN ONE SUCH FAILURE PER YEAR FOR EACH TEN THOUSAND EXEMPT UNITS DISTRIBUTED. NEGLIGIBLE-NOT MORE THAN ONE SUCH FAILURE PER YEAR FOR EACH ONE MILLION EXEMPT UNITS DISTRIBUTED.

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APPENDIX ATABLE OF ORGAN DOSES

Part of body	Column I		Column II		Column III		Column IV	
	μSv	(REM)	μSv	(REM)	μSv	(REM)	μSv	(REM)
Whole body; head and trunk: active blood-forming organs; gonads: or lens of eye.	10	0.001	100	0.01	5000	0.5	1.5E+05	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter.	150	0.015	1500	0.15	75000	7.5	2.0E+06	200
Other organs	30	0.003	300	0.03	15000	1.5	5.0E+05	50

3701:1-46-27 GAS AND AEROSOL DETECTORS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM: REQUIREMENTS FOR LICENSE TO MANUFACTURE, PROCESS, PRODUCE, OR INITIALLY TRANSFER.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, PROCESS, OR PRODUCE GAS AND AEROSOL DETECTORS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM AND DESIGNED TO PROTECT LIFE OR PROPERTY FROM FIRES AND AIRBORNE HAZARDS, OR TO INITIALLY TRANSFER SUCH PRODUCTS FOR USE PURSUANT TO RULE 3701:1-40-13 OF THE ADMINISTRATIVE CODE OR EQUIVALENT REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE, WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE: PROVIDED, HOWEVER, THAT THE REQUIREMENTS OF PARAGRAPHS (A)(2) AND (3) OF RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE DO NOT APPLY TO AN APPLICATION FOR A LICENSE TO TRANSFER BYPRODUCT MATERIAL IN GAS AND AEROSOL DETECTORS MANUFACTURED, PROCESSED OR PRODUCED PURSUANT TO A LICENSE ISSUED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE.
- (B) THE APPLICANT SUBMITS SUFFICIENT INFORMATION RELATING TO THE DESIGN, MANUFACTURE, PROTOTYPE TESTING, QUALITY CONTROL PROCEDURES, LABELING OR MARKING, AND CONDITIONS OF HANDLING, STORAGE, USE, AND DISPOSAL OF THE GAS AND AEROSOL DETECTOR TO DEMONSTRATE THAT THE PRODUCT WILL MEET THE SAFETY CRITERIA SET FORTH IN RULE 3701:1-46-28 OF THIS CHAPTER. THE INFORMATION SHOULD INCLUDE:
 - (1) A DESCRIPTION OF THE PRODUCT AND ITS INTENDED USE OR USES;
 - (2) THE TYPE AND QUANTITY OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN EACH UNIT;
 - (3) CHEMICAL AND PHYSICAL FORM OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IN THE PRODUCT AND CHANGES IN CHEMICAL AND PHYSICAL FORM THAT MAY OCCUR DURING THE USEFUL LIFE OF THE PRODUCT;
 - (4) SOLUBILITY IN WATER AND BODY FLUIDS OF THE FORMS OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IDENTIFIED IN PARAGRAPHS (B) (3) AND (12) OF THIS RULE;
 - (5) DETAILS OF CONSTRUCTION AND DESIGN OF THE PRODUCT AS RELATED TO CONTAINMENT AND SHIELDING OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL OR RADIUM AND OTHER SAFETY FEATURES UNDER NORMAL AND SEVERE CONDITIONS OF HANDLING, STORAGE, USE, AND DISPOSAL OF THE PRODUCT;
 - (6) MAXIMUM EXTERNAL RADIATION LEVELS AT FIVE AND TWENTY FIVE CENTIMETERS FROM ANY EXTERNAL SURFACE OF THE PRODUCT,

AVERAGED OVER AN AREA NOT TO EXCEED TEN SQUARE CENTIMETERS, AND THE METHOD OF MEASUREMENT;

- (7) DEGREE OF ACCESS OF HUMAN BEINGS TO THE PRODUCT DURING NORMAL HANDLING AND USE;
- (8) TOTAL QUANTITY OF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM EXPECTED TO BE DISTRIBUTED IN THE PRODUCT ANNUALLY;
- (9) THE EXPECTED USEFUL LIFE OF THE PRODUCT;
- (10) THE PROPOSED METHODS OF LABELING OR MARKING THE DETECTOR AND ITS POINT-OF-SALE PACKAGE;
- (11) PROCEDURES FOR PROTOTYPE TESTING OF THE PRODUCT TO DEMONSTRATE THE EFFECTIVENESS OF THE CONTAINMENT, SHIELDING, AND OTHER SAFETY FEATURES UNDER BOTH NORMAL AND SEVERE CONDITIONS OF HANDLING, STORAGE, USE, AND DISPOSAL OF THE PRODUCT;
- (12) RESULTS OF THE PROTOTYPE TESTING OF THE PRODUCT, INCLUDING ANY CHANGE IN THE FORM OF THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN THE PRODUCT, THE EXTENT TO WHICH THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM MAY BE RELEASED TO THE ENVIRONMENT, ANY INCREASE IN EXTERNAL RADIATION LEVELS, AND ANY OTHER CHANGES IN SAFETY FEATURES;
- (13) THE ESTIMATED EXTERNAL RADIATION DOSES AND DOSE COMMITMENTS RELEVANT TO THE SAFETY CRITERIA IN RULE 3701:1-46-28 OF THIS CHAPTER AND THE BASIS FOR SUCH ESTIMATES;
- (14) A DETERMINATION THAT THE PROBABILITIES WITH RESPECT TO THE DOSES REFERRED TO IN PARAGRAPH (C) RULE 3701:1-46-28 OF THIS CHAPTER MEET THE CRITERIA OF THAT PARAGRAPH;
- (15) QUALITY CONTROL PROCEDURES TO BE FOLLOWED IN THE FABRICATION OF PRODUCTION LOTS OF THE PRODUCT AND THE QUALITY CONTROL STANDARDS THE PRODUCT WILL BE REQUIRED TO MEET; AND
- (16) ANY ADDITIONAL INFORMATION, INCLUDING EXPERIMENTAL STUDIES AND TESTS, REQUIRED BY THE DIRECTOR.

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3701:1-46-28 GAS AND AEROSOL DETECTORS CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM: SAFETY CRITERIA.

AN APPLICANT FOR A LICENSE UNDER RULE 3701:1-46-27 OF THIS CHAPTER SHALL DEMONSTRATE THAT THE PRODUCT IS DESIGNED AND WILL BE MANUFACTURED SO THAT:

- (A) IN NORMAL USE AND DISPOSAL OF A SINGLE EXEMPT UNIT, AND IN NORMAL HANDLING AND STORAGE OF THE QUANTITIES OF EXEMPT UNITS LIKELY TO ACCUMULATE IN ONE LOCATION DURING MARKETING, DISTRIBUTION, INSTALLATION, AND SERVICING OF THE PRODUCT, IT IS UNLIKELY THAT THE EXTERNAL RADIATION DOSE IN ANY ONE YEAR, OR THE DOSE COMMITMENT RESULTING FROM THE INTAKE OF RADIOACTIVE MATERIAL IN ANY ONE YEAR, TO A SUITABLE SAMPLE OF THE GROUP OF INDIVIDUALS EXPECTED TO BE MOST HIGHLY EXPOSED TO RADIATION OR RADIOACTIVE MATERIAL FROM THE PRODUCT WILL EXCEED THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN I OF APPENDIX A TO THIS CHAPTER.
- (B) IT IS UNLIKELY THAT THERE WILL BE A SIGNIFICANT REDUCTION IN THE EFFECTIVENESS OF THE CONTAINMENT, SHIELDING, OR OTHER SAFETY FEATURES OF THE PRODUCT FROM WEAR AND ABUSE LIKELY TO OCCUR IN NORMAL HANDLING AND USE OF THE PRODUCT DURING ITS USEFUL LIFE.
- (C) IN USE AND DISPOSAL OF A SINGLE EXEMPT UNIT AND IN HANDLING AND STORAGE OF THE QUANTITIES OF EXEMPT UNITS LIKELY TO ACCUMULATE IN ONE LOCATION DURING MARKETING, DISTRIBUTION, INSTALLATION, AND SERVICING OF THE PRODUCT, THE PROBABILITY IS LOW THAT THE CONTAINMENT, SHIELDING, OR OTHER SAFETY FEATURES OF THE PRODUCT WOULD FAIL UNDER SUCH CIRCUMSTANCES THAT A PERSON WOULD RECEIVE AN EXTERNAL RADIATION DOSE OR DOSE COMMITMENT IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN II OF APPENDIX A TO THIS RULE, AND THE PROBABILITY IS NEGLIGIBLE THAT A PERSON WOULD RECEIVE AN EXTERNAL RADIATION DOSE OR DOSE COMMITMENT IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN III OF APPENDIX A TO THIS RULE.

IT IS THE INTENT OF THIS PARAGRAPH THAT AS THE MAGNITUDE OF THE POTENTIAL DOSE INCREASES ABOVE THAT PERMITTED UNDER NORMAL CONDITIONS, THE PROBABILITY THAT ANY INDIVIDUAL WILL RECEIVE SUCH A DOSE MUST DECREASE. THE PROBABILITIES HAVE BEEN EXPRESSED IN GENERAL TERMS TO EMPHASIZE THE APPROXIMATE NATURE OF THE ESTIMATES WHICH ARE TO BE MADE. THE FOLLOWING VALUES MAY BE USED AS GUIDES IN ESTIMATING COMPLIANCE WITH THE CRITERIA: LOW-NOT MORE THAN ONE SUCH FAILURE PER YEAR FOR EACH TEN THOUSAND EXEMPT UNITS DISTRIBUTED. NEGLIGIBLE-NOT MORE THAN ONE SUCH FAILURE PER YEAR FOR EACH ONE MILLION EXEMPT UNITS DISTRIBUTED.

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APPENDIX ATABLE OF ORGAN DOSES

Part of body	Column I		Column II		Column III	
	μSv	(REM)	μSv	(REM)	μSv	(REM)
Whole body; head and trunk: active blood-forming organs; gonads: or lens of eye.	50	0.005	5000	0.5	1.5e+05	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter.	750	0.075	75000	7.5	2.0E+06	200
Other organs	150	0.015	15000	1.5	5.0E+05	50

3701:1-46-29 SCHEDULE A - PROTOTYPE TESTS FOR AUTOMOBILE LOCK ILLUMINATORS.

AN APPLICANT FOR A LICENSE PURSUANT TO RULE 3701:1-46-16 OF THIS CHAPTER TO INSTALL LOCK ILLUMINATORS INTO AUTOMOBILE LOCKS, OR TO INITIALLY TRANSFER LOCK ILLUMINATORS IN AUTOMOBILE LOCKS FOR USE PURSUANT TO RULE 3701:1-40-09 OF THE ADMINISTRATIVE CODE SHALL CONDUCT THE FOLLOWING PROTOTYPE TESTS ON EACH OF FIVE PROTOTYPE DEVICES, CONSISTING OF THE AUTOMOBILE LOCK WITH THE INSTALLED ILLUMINATOR IN THE FOLLOWING ORDER:

- (A) THE DEVICE SHALL BE SUBJECTED TO ONE HUNDRED HOURS OF ACCELERATED WEATHERING IN A SUITABLE WEATHERING MACHINE WHICH SIMULATES THE MOST SEVERE CONDITIONS OF NORMAL USE;
- (B) THE DEVICE SHALL BE DROPPED UPON A CONCRETE OR IRON SURFACE IN A THREE-FOOT FREE GRAVITATIONAL FALL, OR SHALL BE SUBJECTED TO AN EQUIVALENT TREATMENT IN A TEST DEVICE SIMULATING SUCH A FALL. THE DROP TEST SHALL BE REPEATED ONE HUNDRED TIMES FROM RANDOM ORIENTATIONS;
- (C) THE DEVICE SHALL BE ATTACHED TO A VIBRATORY FIXTURE AND VIBRATED AT A RATE OF NOT LESS THAN TWENTY SIX CYCLES PER SECOND AND A VIBRATION ACCELERATION OF NOT LESS THAN TWO G FOR A PERIOD OF NOT LESS THAN ONE HOUR;
- (D) ON COMPLETION OF THE FOREGOING TESTS, THE DEVICE SHALL BE IMMERSSED IN THIRTY INCHES OF WATER FOR TWENTY FOUR HOURS AND SHALL SHOW NO VISIBLE EVIDENCE OF WATER ENTRY INTO THE LOCK ILLUMINATOR. ABSOLUTE PRESSURE OF THE AIR ABOVE THE WATER SHALL THEN BE REDUCED TO ONE INCH OF MERCURY. LOWERED PRESSURE SHALL BE MAINTAINED FOR ONE MINUTE OR UNTIL AIR BUBBLES CEASE TO BE GIVEN OFF BY THE WATER, WHICHEVER IS THE LONGER. PRESSURE SHALL THEN BE INCREASED TO NORMAL ATMOSPHERIC PRESSURE. ANY EVIDENCE OF BUBBLES EMANATING FROM WITHIN THE LOCK ILLUMINATOR, OR WATER ENTERING THE LOCK ILLUMINATOR, SHALL BE CONSIDERED LEAKAGE;
- (E) AFTER EACH OF THE TESTS PRESCRIBED BY THIS RULE, EACH DEVICE SHALL BE EXAMINED FOR EVIDENCE OF PHYSICAL DAMAGE AND FOR LOSS OF TRITIUM OR PROMETHIUM-147. ANY EVIDENCE OF DAMAGE TO OR FAILURE OF ANY DEVICE WHICH COULD AFFECT THE CONTAINMENT OF THE TRITIUM OR PROMETHIUM-147 IN SUCH DEVICES SHALL BE CAUSE FOR REJECTION OF THE DESIGN ON WHICH SUCH PROTOTYPE DEVICES WERE CONSTRUCTED OR MANUFACTURED IF THE DAMAGE OR FAILURE IS ATTRIBUTABLE TO DESIGN DEFECT. LOSS OF TRITIUM OR PROMETHIUM-147 FROM EACH TESTED DEVICE SHALL BE MEASURED BOTH BY SAMPLING THE IMMERSION TEST WATER USED IN PARAGRAPH (D) OF THIS RULE AND BY WIPING WITH FILTER PAPER THE ENTIRE ACCESSIBLE AREA OF THE LOCK ILLUMINATOR. MEASUREMENTS OF TRITIUM OR PROMETHIUM-147 SHALL BE MADE IN AN APPARATUS CALIBRATED TO MEASURE TRITIUM OR PROMETHIUM-147, AS APPROPRIATE. IF MORE THAN 0.1 PERCENT OF THE

ORIGINAL AMOUNT OF TRITIUM OR PROMETHIUM-147 IN THE DEVICE IS FOUND IN THE IMMERSION TEST WATER OF THE TEST IN PARAGRAPH (D) OF THIS RULE, OR IF MORE THAN TWO THOUSAND TWO HUNDRED DISINTEGRATIONS PER MINUTE OF TRITIUM OR PROMETHIUM-147 ON THE FILTER PAPER IS MEASURED AFTER ANY OF THE TESTS IN PARAGRAPHS (A) TO (D) OF THIS RULE THE DEVICE SHALL BE REJECTED.

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3701:1-46-30 BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN DEVICES FOR USE UNDER RULE 3701:1-46-05 OF THIS CHAPTER; REQUIREMENTS FOR LICENSE TO MANUFACTURE, OR INITIALLY TRANSFER.

- (A) AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, OR INITIALLY TRANSFER DEVICES CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-05 OF THIS CHAPTER OR EQUIVALENT REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION , AN AGREEMENT STATE, OR NARM LICENSING STATE WILL BE APPROVED IF:
- (1) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS OF RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
 - (2) THE APPLICANT SUBMITS SUFFICIENT INFORMATION RELATING TO THE DESIGN, MANUFACTURE, PROTOTYPE TESTING, QUALITY CONTROL, LABELS, PROPOSED USES, INSTALLATION, SERVICING, LEAK TESTING, OPERATING AND SAFETY INSTRUCTIONS, AND POTENTIAL HAZARDS OF THE DEVICE TO PROVIDE REASONABLE ASSURANCE THAT:
 - (a) THE DEVICE CAN BE SAFELY OPERATED BY PERSONS NOT HAVING TRAINING IN RADIOLOGICAL PROTECTION;
 - (b) UNDER ORDINARY CONDITIONS OF HANDLING, STORAGE, AND USE OF THE DEVICE, THE BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN THE DEVICE WILL NOT BE RELEASED OR INADVERTENTLY REMOVED FROM THE DEVICE, AND IT IS UNLIKELY THAT ANY PERSON WILL RECEIVE IN ONE YEAR A DOSE IN EXCESS OF TEN PERCENT OF THE ANNUAL LIMITS SPECIFIED IN PARAGRAPH (A) OF RULE 3701:1-38-12 OF THE ADMINISTRATIVE CODE; AND
 - (c) UNDER ACCIDENT CONDITIONS (SUCH AS FIRE AND EXPLOSION) ASSOCIATED WITH HANDLING, STORAGE AND USE OF THE DEVICE, IT IS UNLIKELY THAT ANY PERSON WOULD RECEIVE AN EXTERNAL RADIATION DOSE OR DOSE COMMITMENT IN EXCESS OF THE DOSE TO THE APPROPRIATE ORGAN AS SPECIFIED IN COLUMN IV OF APPENDIX A TO RULE 3701:1-46-26 OF THIS CHAPTER.
 - (3) EACH DEVICE BEARS A DURABLE, LEGIBLE, CLEARLY VISIBLE LABEL OR LABELS APPROVED BY THE DIRECTOR WHICH CONTAIN IN A CLEARLY IDENTIFIED AND SEPARATE STATEMENT:
 - (a) INSTRUCTIONS AND PRECAUTIONS NECESSARY TO ASSURE SAFE INSTALLATION, OPERATION, AND SERVICING OF THE DEVICE (DOCUMENTS SUCH AS OPERATING AND SERVICE MANUALS MAY BE IDENTIFIED IN THE LABEL AND USED TO PROVIDE THIS INFORMATION);

- (b) THE REQUIREMENTS, OR LACK OF REQUIREMENT, FOR LEAK TESTING, OR FOR TESTING ANY ON-OFF MECHANISM AND INDICATOR, INCLUDING THE MAXIMUM TIME INTERVAL FOR SUCH TESTING, AND THE IDENTIFICATION OF RADIOACTIVE MATERIAL BY ISOTOPE, QUANTITY OF RADIOACTIVITY, AND DATE OF DETERMINATION OF THE QUANTITY; AND
- (c) THE INFORMATION CALLED FOR IN THE FOLLOWING STATEMENT IN THE SAME OR SUBSTANTIALLY SIMILAR FORM: DEVICES LICENSED UNDER 10 C.F.R. 32.51 PRIOR TO JANUARY 19, 1975; MAY BEAR LABELS AUTHORIZED BY THE REGULATIONS IN EFFECT ON JANUARY 1, 1975.

- (i) FOR BYPRODUCT MATERIAL:

THE RECEIPT, POSSESSION, USE, AND TRANSFER OF THIS DEVICE MODEL _____, SERIAL NO. _____, ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT AND THE REGULATIONS OF THE U.S. NRC OR OF A STATE WITH WHICH THE NRC HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. THIS LABEL SHALL BE MAINTAINED ON THE DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED. THE MODEL, SERIAL NUMBER, AND THE NAME OF THE MANUFACTURER, OR INITIAL TRANSFEROR MAY BE OMITTED FROM THIS LABEL PROVIDED THE INFORMATION IS ELSEWHERE SPECIFIED IN LABELING AFFIXED TO THE DEVICE.

CAUTION-RADIOACTIVE MATERIAL

 (NAME OF MANUFACTURER, OR INITIAL TRANSFEROR)

- (ii) FOR ACCELERATOR PRODUCED MATERIAL OR RADIUM:

THE RECEIPT, POSSESSION, USE, AND TRANSFER OF THIS DEVICE MODEL _____, SERIAL NO. _____, ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT AND THE REGULATIONS OF A NARM LICENSING STATE. THIS LABEL SHALL BE MAINTAINED ON THE DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED.

CAUTION-RADIOACTIVE MATERIAL

 (NAME OF MANUFACTURER, OR INITIAL TRANSFEROR)

- (4) EACH DEVICE HAVING A SEPARABLE SOURCE HOUSING THAT PROVIDES THE PRIMARY SHIELDING FOR THE SOURCE ALSO BEARS, ON THE SOURCE HOUSING, A DURABLE LABEL CONTAINING THE DEVICE MODEL NUMBER AND SERIAL NUMBER, THE ISOTOPE AND QUANTITY, THE WORDS, "CAUTION - RADIOACTIVE MATERIAL," THE RADIATION SYMBOL DESCRIBED IN PARAGRAPH (A) OF RULE 3701:1-38-18 OF THE ADMINISTRATIVE CODE, AND THE NAME OF THE MANUFACTURER OR INITIAL DISTRIBUTOR.
 - (5) EACH DEVICE MEETING THE CRITERIA OF RULE 3701:1-46-05(C)(12)(a) OF THIS CHAPTER, BEARS A PERMANENT (E.G., EMBOSSED, ETCHED, STAMPED, OR ENGRAVED) LABEL AFFIXED TO THE SOURCE HOUSING IF SEPARABLE, OR THE DEVICE IF THE SOURCE HOUSING IS NOT SEPARABLE, THAT INCLUDES THE WORDS, "CAUTION - RADIOACTIVE MATERIAL," AND, IF PRACTICABLE, THE RADIATION SYMBOL DESCRIBED IN PARAGRAPH (A) OF RULE 3701:1-38-18 OF THE ADMINISTRATIVE CODE.
- (B) IN THE EVENT THE APPLICANT DESIRES THAT THE DEVICE BE REQUIRED TO BE TESTED AT INTERVALS LONGER THAN SIX MONTHS, EITHER FOR PROPER OPERATION OF THE ON-OFF MECHANISM AND INDICATOR, IF ANY, OR FOR LEAKAGE OF RADIOACTIVE MATERIAL OR FOR BOTH, HE SHALL INCLUDE IN THIS APPLICATION SUFFICIENT INFORMATION TO DEMONSTRATE THAT SUCH LONGER INTERVAL IS JUSTIFIED BY PERFORMANCE CHARACTERISTICS OF THE DEVICE OR SIMILAR DEVICES, AND BY DESIGN FEATURES WHICH HAVE A SIGNIFICANT BEARING ON THE PROBABILITY OR CONSEQUENCES OF LEAKAGE OF RADIOACTIVE MATERIAL FROM THE DEVICE OR FAILURE OF THE ON-OFF MECHANISM AND INDICATOR. IN DETERMINING THE ACCEPTABLE INTERVAL FOR THE TEST FOR LEAKAGE OF RADIOACTIVE MATERIAL, THE DIRECTOR WILL CONSIDER INFORMATION WHICH INCLUDES, BUT IS NOT LIMITED TO:
- (1) PRIMARY CONTAINMENT (SOURCE CAPSULE);
 - (2) PROTECTION OF PRIMARY CONTAINMENT;
 - (3) METHOD OF SEALING CONTAINMENT;
 - (4) CONTAINMENT CONSTRUCTION MATERIALS;
 - (5) FORM OF CONTAINED RADIOACTIVE MATERIAL;
 - (6) MAXIMUM TEMPERATURE WITHSTOOD DURING PROTOTYPE TESTS;
 - (7) MAXIMUM PRESSURE WITHSTOOD DURING PROTOTYPE TESTS;
 - (8) MAXIMUM QUANTITY OF CONTAINED RADIOACTIVE MATERIAL;
 - (9) RADIOTOXICITY OF CONTAINED RADIOACTIVE MATERIAL; AND

(10) OPERATING EXPERIENCE WITH IDENTICAL DEVICES OR SIMILARLY DESIGNED AND CONSTRUCTED DEVICES.

(C) IN THE EVENT THE APPLICANT DESIRES THAT THE GENERAL LICENSEE UNDER RULE 3701:1-46-05 OF THIS CHAPTER, OR UNDER EQUIVALENT REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION, AN AGREEMENT STATE, OR NARM LICENSING STATE BE AUTHORIZED TO INSTALL THE DEVICE, COLLECT THE SAMPLE TO BE ANALYZED BY A SPECIFIC LICENSEE FOR LEAKAGE OF RADIOACTIVE MATERIAL, SERVICE THE DEVICE, TEST THE ON-OFF MECHANISM AND INDICATOR, OR REMOVE THE DEVICE FROM INSTALLATION, THE APPLICANT SHALL INCLUDE IN THE APPLICATION WRITTEN INSTRUCTIONS TO BE FOLLOWED BY THE GENERAL LICENSEE, ESTIMATED CALENDAR QUARTER DOSES ASSOCIATED WITH SUCH ACTIVITY OR ACTIVITIES, AND THE BASES FOR THESE ESTIMATES. THE SUBMITTED INFORMATION MUST DEMONSTRATE THAT PERFORMANCE OF THIS ACTIVITY OR ACTIVITIES BY AN INDIVIDUAL UNTRAINED IN RADIOLOGICAL PROTECTION, IN ADDITION TO OTHER HANDLING, STORAGE, AND USE OF DEVICES UNDER THE GENERAL LICENSE, IS UNLIKELY TO CAUSE THAT INDIVIDUAL TO RECEIVE A DOSE IN EXCESS OF TEN PERCENT OF THE ANNUAL LIMITS SPECIFIED IN PARAGRAPH (A) OF RULE 3701:1-38-12 OF THE ADMINISTRATIVE CODE.

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3701:1-46-31 BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN DEVICES FOR USE UNDER RULE 3701:1-46-05 OF THIS CHAPTER: CONDITIONS OF LICENSES.

- (A) IF A DEVICE CONTAINING BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IS TO BE TRANSFERRED FOR USE UNDER THE GENERAL LICENSE CONTAINED IN RULE 3701:1-46-05 OF THIS CHAPTER, EACH PERSON THAT IS LICENSED UNDER RULE 3701:1-46-30 OF THIS CHAPTER SHALL PROVIDE THE INFORMATION SPECIFIED IN THIS PARAGRAPH TO EACH PERSON TO WHOM A DEVICE IS TO BE TRANSFERRED. THIS INFORMATION MUST BE PROVIDED BEFORE THE DEVICE MAY BE TRANSFERRED. IN THE CASE OF A TRANSFER THROUGH AN INTERMEDIATE PERSON, THE INFORMATION MUST ALSO BE PROVIDED TO THE INTENDED USER PRIOR TO THE INITIAL TRANSFER TO THE INTERMEDIATE PERSON. THE REQUIRED INFORMATION INCLUDES:
- (1) A COPY OF RULE 3701:1-46-05 OF THIS CHAPTER; IF PARAGRAPHS (C)(2) THROUGH (4), OR (C)(12) OF RULE 3701:1-46-05 OF THIS CHAPTER DO NOT APPLY TO THE PARTICULAR DEVICE, THOSE PARAGRAPHS MAY BE OMITTED.
 - (2) A COPY OF RULE 3701:1-46-03, PARAGRAPHS (A) AND (B) OF RULE 3701:1-38-21, AND 3701:1-40-21 OF THE ADMINISTRATIVE CODE;
 - (3) A LIST OF THE SERVICES THAT CAN ONLY BE PERFORMED BY A SPECIFIC LICENSEE; AND
 - (4) INFORMATION ON ACCEPTABLE DISPOSAL OPTIONS INCLUDING ESTIMATED COSTS OF DISPOSAL AT THE TIME OF THE PURCHASE; AND
- (B) IF BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM IS TO BE TRANSFERRED IN A DEVICE FOR USE UNDER AN EQUIVALENT GENERAL LICENSE OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION, AN AGREEMENT STATE OR NARM LICENSING STATE, EACH PERSON THAT IS LICENSED UNDER RULE 3701:1-46-30 OF THIS CHAPTER SHALL PROVIDE THE INFORMATION SPECIFIED IN THIS PARAGRAPH TO EACH PERSON TO WHOM A DEVICE IS TO BE TRANSFERRED. THIS INFORMATION MUST BE PROVIDED BEFORE THE DEVICE MAY BE TRANSFERRED. IN THE CASE OF A TRANSFER THROUGH AN INTERMEDIATE PERSON, THE INFORMATION MUST ALSO BE PROVIDED TO THE INTENDED USER PRIOR TO INITIAL TRANSFER TO THE INTERMEDIATE PERSON. THE REQUIRED INFORMATION INCLUDES:
- (1) A COPY OF PARAGRAPHS (A) AND (B) OF RULE 3701:1-38-21, RULE 3701:1-40-21, RULE 3701:1-46-03, AND RULE 3701:1-46-05 OF THE ADMINISTRATIVE CODE;
 - (2) A LIST OF THE SERVICES THAT CAN ONLY BE PERFORMED BY A SPECIFIC LICENSEE;

- (3) INFORMATION ON ACCEPTABLE DISPOSAL OPTIONS INCLUDING ESTIMATED COSTS OF DISPOSAL AT THE TIME OF THE PURCHASE; AND
 - (4) THE NAME, ADDRESS, AND PHONE NUMBER OF THE CONTACT AT THE UNITED STATES NUCLEAR REGULATORY COMMISSION, THE AGREEMENT STATE REGULATORY AGENCY OR NARM LICENSING STATE REGULATORY AGENCY FROM WHICH ADDITIONAL INFORMATION MAY BE OBTAINED.
- (C) AN ALTERNATE APPROACH TO INFORMING CUSTOMERS MAY BE PROPOSED BY THE LICENSEE FOR APPROVAL BY THE DIRECTOR.
- (D) EACH DEVICE THAT IS TRANSFERRED **AFTER (INSERT DATE ONE YEAR AFTER THE EFFECTIVE DATE OF THIS RULE)** MUST MEET THE LABELING REQUIREMENTS IN PARAGRAPHS (A)(3) THROUGH (A)(5) OF RULE 3701:46-30 OF THIS CHAPTER.
- (E) IF A NOTIFICATION OF BANKRUPTCY HAS BEEN MADE UNDER PARAGRAPH (F) OF RULE 3701:1-40-16 OF THE ADMINISTRATIVE CODE, OR THE LICENSE IS TO BE TERMINATED, EACH PERSON LICENSED UNDER RULE 3701:1-46-30 OF THIS CHAPTER SHALL PROVIDE, UPON REQUEST, TO THE DIRECTOR, AND IF APPROPRIATE, TO THE UNITED STATES NUCLEAR REGULATORY COMMISSION AND ANY APPROPRIATE AGREEMENT STATE OR NARM LICENSING STATE, RECORDS OF FINAL DISPOSITION REQUIRED UNDER PARAGRAPH (C) OF RULE 3701:1-46-32 OF THIS CHAPTER.

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3701:1-46-32 BYPRODUCT, ACCELERATOR PRODUCED MATERIAL, OR RADIUM CONTAINED IN DEVICES FOR USE UNDER RULE 3701:1-46-05 OF THIS CHAPTER: MATERIAL TRANSFER REPORTS AND RECORDS.

EACH PERSON LICENSED UNDER RULE 3701:1-46-30 OF THIS CHAPTER TO INITIALLY TRANSFER DEVICES TO GENERALLY LICENSED PERSONS SHALL:

- (A) REPORT ALL TRANSFERS OF DEVICES TO PERSONS FOR USE UNDER THE GENERAL LICENSE IN RULE 3701:1-46-05 OF THIS CHAPTER AND ALL RECEIPTS OF DEVICES FROM PERSONS LICENSED UNDER RULE 3701:1-46-05 OF THIS CHAPTER TO THE DIRECTOR IN A CLEAR AND LEGIBLE REPORT CONTAINING ALL OF THE DATA REQUIRED BY THE FORM.
 - (1) THE REQUIRED INFORMATION INCLUDES--
 - (a) THE IDENTITY OF EACH GENERAL LICENSEE BY NAME AND MAILING ADDRESS FOR THE LOCATION OF USE; IF THERE IS NO MAILING ADDRESS FOR THE LOCATION OF USE, AN ALTERNATE ADDRESS FOR THE GENERAL LICENSEE SHALL BE SUBMITTED ALONG WITH INFORMATION ON THE ACTUAL LOCATION OF USE.
 - (b) THE NAME, TITLE, AND PHONE NUMBER OF THE PERSON IDENTIFIED BY THE GENERAL LICENSEE AS HAVING KNOWLEDGE OF AND AUTHORITY TO TAKE REQUIRED ACTIONS TO ENSURE COMPLIANCE WITH THE APPROPRIATE REGULATIONS AND REQUIREMENTS;
 - (c) THE DATE OF TRANSFER;
 - (d) THE TYPE, MODEL NUMBER, AND SERIAL NUMBER OF THE DEVICE TRANSFERRED; AND
 - (e) THE QUANTITY AND TYPE OF RADIOACTIVE MATERIAL CONTAINED IN THE DEVICE.
 - (2) IF ONE OR MORE INTERMEDIATE PERSONS WILL TEMPORARILY POSSESS THE DEVICE AT THE INTENDED PLACE OF USE BEFORE ITS POSSESSION BY THE USER, THE REPORT MUST INCLUDE THE SAME INFORMATION FOR BOTH THE INTENDED USER AND EACH INTERMEDIATE PERSON, AND CLEARLY DESIGNATE THE INTERMEDIATE PERSON(S).
 - (3) FOR DEVICES RECEIVED FROM A GENERAL LICENSEE UNDER RULE 3701:1-46-05 OF THIS CHAPTER, THE REPORT MUST INCLUDE THE IDENTITY OF THE GENERAL LICENSEE BY NAME AND ADDRESS, THE TYPE, MODEL NUMBER, AND SERIAL NUMBER OF THE DEVICE RECEIVED, THE DATE OF RECEIPT, AND, IN THE CASE OF DEVICES

NOT INITIALLY TRANSFERRED BY THE REPORTING LICENSEE, THE NAME OF THE MANUFACTURER OR INITIAL TRANSFEROR.

- (4) IF THE LICENSEE MAKES CHANGES TO A DEVICE POSSESSED BY A GENERAL LICENSEE UNDER RULE 3701:1-46-05 OF THIS CHAPTER, SUCH THAT THE LABEL MUST BE CHANGED TO UPDATE REQUIRED INFORMATION, THE REPORT MUST IDENTIFY THE GENERAL LICENSEE, THE DEVICE, AND THE CHANGES TO INFORMATION ON THE DEVICE LABEL.
 - (5) THE REPORT MUST COVER EACH CALENDAR QUARTER, MUST BE FILED WITHIN THIRTY DAYS OF THE END OF THE CALENDAR QUARTER, AND MUST CLEARLY INDICATE THE PERIOD COVERED BY THE REPORT.
 - (6) THE REPORT MUST CLEARLY IDENTIFY THE SPECIFIC LICENSEE SUBMITTING THE REPORT AND INCLUDE THE LICENSE NUMBER OF THE SPECIFIC LICENSEE.
 - (7) IF NO TRANSFERS HAVE BEEN MADE TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-05 OF THIS CHAPTER DURING THE REPORTING PERIOD, THE REPORT MUST SO INDICATE.
- (B) REPORT ALL TRANSFERS OF DEVICES TO PERSONS FOR USE UNDER A GENERAL LICENSE IN THE UNITED STATES NUCLEAR REGULATORY COMMISSION'S, AN AGREEMENT STATE'S OR NARM LICENSING STATE'S REGULATIONS THAT ARE EQUIVALENT TO RULE 3701:1-46-05 OF THIS CHAPTER AND ALL RECEIPTS OF DEVICES FROM GENERAL LICENSEES IN UNITED STATES NUCLEAR REGULATORY COMMISSION, AGREEMENT STATE OR NARM LICENSING STATE JURISDICTION TO THE RESPONSIBLE AGENCY, UNITED STATES NUCLEAR REGULATORY COMMISSION, AGREEMENT STATE OR NARM LICENSING STATE. THE REPORT MUST BE IN A CLEAR AND LEGIBLE FORMAT CONTAINING ALL OF THE DATA REQUIRED BY THE FORM.
- (1) THE REQUIRED INFORMATION FOR TRANSFERS TO GENERAL LICENSEES INCLUDES—
 - (a) THE IDENTITY OF EACH GENERAL LICENSEE BY NAME AND MAILING ADDRESS FOR THE LOCATION OF USE; IF THERE IS NO MAILING ADDRESS FOR THE LOCATION OF USE, AN ALTERNATE ADDRESS FOR THE GENERAL LICENSEE SHALL BE SUBMITTED ALONG WITH INFORMATION ON THE ACTUAL LOCATION OF USE.
 - (b) THE NAME, TITLE, AND PHONE NUMBER OF THE PERSON IDENTIFIED BY THE GENERAL LICENSEE AS HAVING KNOWLEDGE OF AND AUTHORITY TO TAKE REQUIRED

ACTIONS TO ENSURE COMPLIANCE WITH THE APPROPRIATE REGULATIONS AND REQUIREMENTS;

- (c) THE DATE OF TRANSFER;
 - (d) THE TYPE, MODEL NUMBER, AND SERIAL NUMBER OF THE DEVICE TRANSFERRED; AND
 - (e) THE QUANTITY AND TYPE OF RADIOACTIVE MATERIAL CONTAINED IN THE DEVICE.
- (2) IF ONE OR MORE INTERMEDIATE PERSONS WILL TEMPORARILY POSSESS THE DEVICE AT THE INTENDED PLACE OF USE BEFORE ITS POSSESSION BY THE USER, THE REPORT MUST INCLUDE THE SAME INFORMATION FOR BOTH THE INTENDED USER AND EACH INTERMEDIATE PERSON, AND CLEARLY DESIGNATE THE INTERMEDIATE PERSON(S).
 - (3) FOR DEVICES RECEIVED FROM A GENERAL LICENSEE, THE REPORT MUST THE IDENTITY OF THE GENERAL LICENSEE BY NAME AND ADDRESS, THE TYPE, MODEL NUMBER, AND SERIAL NUMBER OF THE DEVICE RECEIVED, THE DATE OF RECEIPT, AND, IN THE CASE OF DEVICES NOT INITIALLY TRANSFERRED BY THE REPORTING LICENSEE, THE NAME OF THE MANUFACTURER OR INITIAL TRANSFEROR.
 - (4) IF THE LICENSEE MAKES CHANGES TO A DEVICE POSSESSED BY A GENERAL LICENSEE, SUCH THAT THE LABEL MUST BE CHANGED TO UPDATE REQUIRED INFORMATION, THE REPORT MUST IDENTIFY THE GENERAL LICENSEE, THE DEVICE, AND THE CHANGES TO INFORMATION ON THE DEVICE LABEL.
 - (5) THE REPORT MUST COVER EACH CALENDAR QUARTER, MUST BE FILED WITHIN THIRTY DAYS OF THE END OF THE CALENDAR QUARTER, AND MUST CLEARLY INDICATE THE PERIOD COVERED BY THE REPORT.
 - (6) THE REPORT MUST CLEARLY IDENTIFY THE SPECIFIC LICENSEE SUBMITTING THE REPORT AND MUST INCLUDE THE LICENSE NUMBER OF THE SPECIFIC LICENSEE.
 - (7) IF NO TRANSFERS HAVE BEEN MADE TO OR FROM THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR A PARTICULAR AGREEMENT STATE OR NARM LICENSING STATE DURING THE REPORTING PERIOD, THIS INFORMATION SHALL BE REPORTED TO THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR THE RESPONSIBLE AGREEMENT STATE OR NARM LICENSING STATE AGENCY UPON REQUEST OF THE AGENCY.

- (C) KEEP RECORDS OF ALL TRANSFERS AND ALL RECEIPTS OF DEVICES FOR EACH GENERAL LICENSEE INCLUDING ALL THE INFORMATION IN THE REPORTS REQUIRED BY THIS RULE. RECORDS REQUIRED BY THIS PARAGRAPH MUST BE KEPT FOR A PERIOD OF THREE YEARS FOLLOWING THE DATE OF THE RECORDED EVENT.

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3701:1-46-33 LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT: REQUIREMENTS FOR LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR INITIALLY TRANSFER.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR INITIALLY TRANSFER LUMINOUS SAFETY DEVICES CONTAINING TRITIUM OR PROMETHIUM-147 FOR USE IN AIRCRAFT, FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-07 OF THIS CHAPTER, WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
- (B) THE APPLICANT SUBMITS SUFFICIENT INFORMATION REGARDING EACH DEVICE PERTINENT TO EVALUATION OF THE POTENTIAL RADIATION EXPOSURE, INCLUDING:
 - (1) CHEMICAL AND PHYSICAL FORM AND MAXIMUM QUANTITY OF TRITIUM OR PROMETHIUM-147 IN EACH DEVICE;
 - (2) DETAILS OF CONSTRUCTION AND DESIGN;
 - (3) DETAILS OF THE METHOD OF BINDING OR CONTAINING THE TRITIUM OR PROMETHIUM-147;
 - (4) PROCEDURES FOR AND RESULTS OF PROTOTYPE TESTING TO DEMONSTRATE THAT THE TRITIUM OR PROMETHIUM-147 WILL NOT BE RELEASED TO THE ENVIRONMENT UNDER THE MOST SEVERE CONDITIONS LIKELY TO BE ENCOUNTERED IN NORMAL USE;
 - (5) ANY QUALITY CONTROL PROCEDURES PROPOSED AS ALTERNATIVES TO THOSE PRESCRIBED BY RULE 3701:1-46-35 OF THIS CHAPTER;
 - (6) ANY ADDITIONAL INFORMATION, INCLUDING EXPERIMENTAL STUDIES AND TESTS, REQUIRED BY THE DIRECTOR TO FACILITATE A DETERMINATION OF THE SAFETY OF THE DEVICE.
- (C) EACH DEVICE WILL CONTAIN NO MORE THAN THREE HUNDRED SEVENTY GIGABECQUERELS (TEN CURIES) OF TRITIUM OR 11.1 GIGABECQUERELS (THREE HUNDRED MILLICURIES) OF PROMETHIUM-147. THE LEVELS OF RADIATION FROM EACH DEVICE CONTAINING PROMETHIUM-147 WILL NOT EXCEED FIVE MICROGRAYS (0.5 MILLIRAD) PER HOUR AT TEN CENTIMETERS FROM ANY SURFACE WHEN MEASURED THROUGH FIFTY MILLIGRAMS PER SQUARE CENTIMETER OF ABSORBER.
- (D) THE DIRECTOR DETERMINES THAT:
 - (1) THE METHOD OF INCORPORATION AND BINDING OF THE TRITIUM OR PROMETHIUM-147 IN THE DEVICE IS SUCH THAT THE TRITIUM OR PROMETHIUM-147 WILL NOT BE RELEASED UNDER THE MOST SEVERE

CONDITIONS WHICH ARE LIKELY TO BE ENCOUNTERED IN NORMAL USE AND HANDLING OF THE DEVICE;

- (2) THE TRITIUM OR PROMETHIUM-147 IS INCORPORATED OR ENCLOSED SO AS TO PRECLUDE DIRECT PHYSICAL CONTACT BY ANY PERSON WITH IT;
- (3) THE DEVICE IS SO DESIGNED THAT IT CANNOT EASILY BE DISASSEMBLED; AND
- (4) THE DEVICE HAS BEEN SUBJECTED TO AND HAS SATISFACTORILY PASSED THE PROTOTYPE TESTS PRESCRIBED BY RULE 3701:1-46-45 OF THIS CHAPTER.

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3701:1-46-34 LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT: LABELING OF DEVICES.

(A) A PERSON LICENSED UNDER RULE 3701:1-46-33 OF THIS CHAPTER TO MANUFACTURE, ASSEMBLE, OR INITIALLY TRANSFER DEVICES CONTAINING TRITIUM OR PROMETHIUM-147 FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-07 OF THIS CHAPTER SHALL, EXCEPT AS PROVIDED IN PARAGRAPH (B) OF THIS RULE, AFFIX TO EACH DEVICE A LABEL CONTAINING THE RADIATION SYMBOL PRESCRIBED BY RULE 3701:1-38-18 OF THE ADMINISTRATIVE CODE, SUCH OTHER INFORMATION AS MAY BE REQUIRED BY THE DIRECTOR INCLUDING DISPOSAL INSTRUCTIONS WHEN APPROPRIATE, AND THE FOLLOWING OR A SUBSTANTIALLY SIMILAR STATEMENT WHICH CONTAINS THE INFORMATION CALLED FOR IN THE FOLLOWING STATEMENT:

- (1) DEVICES LICENSED UNDER 10 C.F.R. 32.53 PRIOR TO JANUARY 19, 1975 MAY BEAR LABELS AUTHORIZED BY THE REGULATIONS IN EFFECT ON JANUARY 1, 1975.
- (2) THE RECEIPT, POSSESSION, USE, AND TRANSFER OF THIS DEVICE, MODEL _____, SERIAL NO. _____, CONTAINING _____ (IDENTITY AND QUANTITY OF RADIOACTIVE MATERIAL) ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT AND THE REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR OF A STATE WITH WHICH THE UNITED STATES NUCLEAR REGULATORY COMMISSION HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. DO NOT REMOVE THIS LABEL.

CAUTION-RADIOACTIVE MATERIAL

(NAME OF MANUFACTURER, ASSEMBLER, OR INITIAL TRANSFEROR.)
THE MODEL, SERIAL NUMBER, AND NAME OF MANUFACTURER, ASSEMBLER, OR INITIAL TRANSFEROR MAY BE OMITTED FROM THIS LABEL PROVIDED THEY ARE ELSEWHERE SPECIFIED IN LABELING AFFIXED TO THE DEVICE.

(B) IF THE DIRECTOR DETERMINES THAT IT IS NOT FEASIBLE TO AFFIX A LABEL TO THE DEVICE CONTAINING ALL THE INFORMATION CALLED FOR IN PARAGRAPH (A) OF THIS RULE, HE/SHE MAY WAIVE THE REQUIREMENTS OF THAT PARAGRAPH AND REQUIRE IN LIEU THEREOF THAT:

- (1) A LABEL BE AFFIXED TO THE DEVICE IDENTIFYING:
 - (a) THE MANUFACTURER, ASSEMBLER, OR INITIAL TRANSFEROR; AND
 - (b) THE TYPE OF RADIOACTIVE MATERIAL; AND
- (2) A LEAFLET BEARING THE FOLLOWING INFORMATION BE ENCLOSED IN OR ACCOMPANY THE CONTAINER IN WHICH THE DEVICE IS SHIPPED:

- (a) THE NAME OF THE MANUFACTURER, ASSEMBLER, OR INITIAL TRANSFEROR,
- (b) THE TYPE AND QUANTITY OF RADIOACTIVE MATERIAL,
- (c) THE MODEL NUMBER,
- (d) A STATEMENT THAT THE RECEIPT, POSSESSION, USE, AND TRANSFER OF THE DEVICE ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT AND THE REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR OF AN AGREEMENT STATE, AND
- (e) SUCH OTHER INFORMATION AS MAY BE REQUIRED BY THE DIRECTOR, INCLUDING DISPOSAL INSTRUCTIONS WHEN APPROPRIATE.

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3701:1-46-35 LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT: QUALITY ASSURANCE; PROHIBITION OF TRANSFER.

- (A) EACH PERSON LICENSED UNDER RULE 3701:1-46-33 OF THIS CHAPTER SHALL VISUALLY INSPECT EACH DEVICE AND SHALL REJECT ANY WHICH HAS AN OBSERVABLE PHYSICAL DEFECT THAT COULD AFFECT CONTAINMENT OF THE TRITIUM OR PROMETHIUM-147.
- (B) EACH PERSON LICENSED UNDER RULE 3701:1-46-33 OF THIS CHAPTER SHALL TAKE A RANDOM SAMPLE OF THE SIZE REQUIRED BY THE TABLE IN RULE 3701:1-46-48 OF THIS CHAPTER FOR LOT TOLERANCE PERCENT DEFECTIVE OF FIVE PERCENT FROM EACH INSPECTION LOT, AND SHALL SUBJECT EACH UNIT IN THE SAMPLE TO THE FOLLOWING TESTS:
 - (1) EACH DEVICE SHALL BE IMMERSSED IN THIRTY INCHES OF WATER FOR TWENTY-FOUR HOURS AND SHALL SHOW NO VISIBLE EVIDENCE OF WATER ENTRY. ABSOLUTE PRESSURE OF THE AIR ABOVE THE WATER SHALL THEN BE REDUCED TO ONE INCH OF MERCURY. LOWERED PRESSURE SHALL BE MAINTAINED FOR ONE MINUTE OR UNTIL AIR BUBBLES CEASE TO BE GIVEN OFF BY THE WATER, WHICHEVER IS THE LONGER. PRESSURE SHALL THEN BE INCREASED TO NORMAL ATMOSPHERIC PRESSURE. ANY DEVICE WHICH LEAKS AS EVIDENCED BY BUBBLES EMANATING FROM WITHIN THE DEVICE, OR WATER ENTERING THE DEVICE, SHALL BE CONSIDERED AS A DEFECTIVE UNIT.
 - (2) THE IMMERSION TEST WATER FROM THE PRECEDING TEST IN PARAGRAPH (B)(1) OF THIS RULE SHALL BE MEASURED FOR TRITIUM OR PROMETHIUM-147 CONTENT BY AN APPARATUS THAT HAS BEEN CALIBRATED TO MEASURE TRITIUM OR PROMETHIUM-147, AS APPROPRIATE. IF MORE THAN 0.1 PERCENT OF THE ORIGINAL AMOUNT OF TRITIUM OR PROMETHIUM-147 IN ANY DEVICE IS FOUND TO HAVE LEAKED INTO THE IMMERSION TEST WATER, THE LEAKING DEVICE SHALL BE CONSIDERED AS A DEFECTIVE UNIT.
 - (3) THE LEVELS OF RADIATION FROM EACH DEVICE CONTAINING PROMETHIUM-147 SHALL BE MEASURED. ANY DEVICE WHICH HAS A RADIATION LEVEL IN EXCESS OF FIVE MICROGRAYS (0.5 IRAD) PER HOUR AT TEN CENTIMETERS FROM ANY SURFACE WHEN MEASURED THROUGH FIFTY MILLIGRAMS PER SQUARE CENTIMETER OF ABSORBER, SHALL BE CONSIDERED AS A DEFECTIVE UNIT.
- (C) AN APPLICATION FOR A LICENSE OR FOR AMENDMENT OF A LICENSE MAY INCLUDE A DESCRIPTION OF PROCEDURES PROPOSED AS ALTERNATIVES TO THOSE PRESCRIBED BY PARAGRAPH (B) OF THIS RULE, AND PROPOSED CRITERIA FOR ACCEPTANCE UNDER THOSE PROCEDURES. THE DIRECTOR WILL APPROVE THE PROPOSED ALTERNATIVE PROCEDURES IF THE APPLICANT DEMONSTRATES THAT:

- (1) THEY WILL CONSIDER DEFECTIVE ANY SAMPLED DEVICE WHICH HAS A LEAKAGE RATE EXCEEDING ___PERCENT OF THE ORIGINAL QUANTITY OF TRITIUM OR PROMETHIUM 147 IN ANY TWENTY FOUR HOUR PERIOD; AND
 - (2) THE OPERATING CHARACTERISTIC CURVE OR CONFIDENCE INTERVAL ESTIMATE FOR THE ALTERNATIVE PROCEDURES PROVIDES A LOT TOLERANCE PERCENT DEFECTIVE OF FIVE PERCENT AT THE CONSUMER'S RISK OF 0.10.
- (D) NO PERSON LICENSED UNDER RULE 3701:1-46-33 OF THIS CHAPTER SHALL TRANSFER TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-07 OF THIS CHAPTER:
- (1) ANY LUMINOUS SAFETY DEVICE WHICH HAS BEEN TESTED AND FOUND DEFECTIVE UNDER THE CRITERIA AND PROCEDURES SPECIFIED IN THIS RULE, UNLESS THE DEFECTIVE UNITS HAVE BEEN REPAIRED OR REWORKED AND HAVE THEN MET THE TESTS SET OUT IN PARAGRAPH (B) OF THIS RULE; OR
 - (2) ANY INSPECTION LOT WHICH HAS BEEN REJECTED AS A RESULT OF THE PROCEDURES IN RULE 3701:1-46-48 OF THIS CHAPTER OR ALTERNATIVE PROCEDURES IN PARAGRAPH (C) OF THIS RULE, UNLESS THE DEFECTIVE UNITS HAVE BEEN SORTED AND REMOVED OR HAVE BEEN REPAIRED OR REWORKED AND HAVE THEN MET THE TESTS SET OUT IN PARAGRAPH (B) OF THIS RULE.

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Public Health Council

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3701:1-46-36 LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT: MATERIAL TRANSFER REPORTS.

EACH PERSON LICENSED UNDER RULE 3701:1-46-33 OF THIS CHAPTER SHALL FILE AN ANNUAL REPORT WITH THE

OHIO DEPARTMENT OF HEALTH, BUREAU OS RADIATION PROTECTION

35 EAST CHESTNUT STREET, SEVENTH FLOOR

POST OFFICE BOX 118

COLUMBUS, OHIO 43216-0118

AND PROVIDE A COPY TO DIRECTOR OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS, UNITED STATES NUCLEAR REGULATORY COMMISSION, WASHINGTON, D.C. 20555-0001, WHICH MUST STATE THE TOTAL QUANTITY OF TRITIUM OR PROMETHIUM-147 TRANSFERRED TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-07 OF THIS CHAPTER. THE REPORT MUST IDENTIFY EACH GENERAL LICENSEE BY NAME, STATE THE KINDS AND NUMBERS OF LUMINOUS DEVICES TRANSFERRED, AND SPECIFY THE QUANTITY OF TRITIUM OR PROMETHIUM-147 IN EACH KIND OF DEVICE. EACH REPORT MUST COVER THE YEAR ENDING JUNE 30 AND MUST BE FILED WITHIN THIRTY (30) DAYS THEREAFTER.

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3701:1-46-37 CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM: REQUIREMENTS FOR LICENSE TO MANUFACTURE OR INITIALLY TRANSFER.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE OR INITIALLY TRANSFER CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM, FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-08 OF THIS CHAPTER, WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS OF RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
- (B) THE APPLICANT SUBMITS SUFFICIENT INFORMATION REGARDING EACH TYPE OF CALIBRATION OR REFERENCE SOURCE PERTINENT TO EVALUATION OF THE POTENTIAL RADIATION EXPOSURE, INCLUDING:
 - (1) CHEMICAL AND PHYSICAL FORM AND MAXIMUM QUANTITY OF AMERICIUM-241 OR RADIUM IN THE SOURCE;
 - (2) DETAILS OF CONSTRUCTION AND DESIGN;
 - (3) DETAILS OF THE METHOD OF INCORPORATION AND BINDING OF THE AMERICIUM-241 OR RADIUM IN THE SOURCE;
 - (4) PROCEDURES FOR AND RESULTS OF PROTOTYPE TESTING OF SOURCES, WHICH ARE DESIGNED TO CONTAIN MORE THAN ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241 OR RADIUM, TO DEMONSTRATE THAT THE AMERICIUM-241 OR RADIUM CONTAINED IN EACH SOURCE WILL NOT BE RELEASED OR BE REMOVED FROM THE SOURCE UNDER NORMAL CONDITIONS OF USE;
 - (5) DETAILS OF QUALITY CONTROL PROCEDURES TO BE FOLLOWED IN MANUFACTURE OF THE SOURCE;
 - (6) DESCRIPTION OF LABELING TO BE AFFIXED TO THE SOURCE OR THE STORAGE CONTAINER FOR THE SOURCE;
 - (7) ANY ADDITIONAL INFORMATION, INCLUDING EXPERIMENTAL STUDIES AND TESTS, REQUIRED BY THE DIRECTOR TO FACILITATE A DETERMINATION OF THE SAFETY OF THE SOURCE.
- (C) EACH SOURCE WILL CONTAIN NO MORE THAN ONE HUNDRED EIGHTY FIVE KILOBECQUERELS (FIVE MICROCURIES) OF AMERICIUM-241 OR RADIUM.
- (D) THE DIRECTOR DETERMINES, WITH RESPECT TO ANY TYPE OF SOURCE CONTAINING MORE THAN ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241, OR RADIUM THAT:
 - (1) THE METHOD OF INCORPORATION AND BINDING OF THE AMERICIUM-241 OR RADIUM IN THE SOURCE IS SUCH THAT THE AMERICIUM-241 OR RADIUM WILL NOT BE RELEASED OR BE

REMOVED FROM THE SOURCE UNDER NORMAL CONDITIONS OF USE
AND HANDLING OF THE SOURCE; AND

- (2) THE SOURCE HAS BEEN SUBJECTED TO AND HAS SATISFACTORILY
PASSED THE PROTOTYPE TESTS PRESCRIBED BY RULE 3701:1-46-46
OF THIS CHAPTER.

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3701:1-46-38 CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM: LABELING OF DEVICES.

EACH PERSON LICENSED UNDER RULE 3701:1-46-37 OF THIS CHAPTER SHALL AFFIX TO EACH SOURCE, OR STORAGE CONTAINER FOR THE SOURCE, A LABEL WHICH SHALL CONTAIN SUFFICIENT INFORMATION RELATIVE TO SAFE USE AND STORAGE OF THE SOURCE AND SHALL INCLUDE THE FOLLOWING STATEMENT OR A SUBSTANTIALLY SIMILAR STATEMENT WHICH CONTAINS THE INFORMATION CALLED FOR IN THE FOLLOWING STATEMENT:

SOURCES LICENSED UNDER 10 C.F.R. 32.57 PRIOR TO JANUARY 19, 1975, MAY BEAR LABELS AUTHORIZED BY THE REGULATIONS IN EFFECT ON JANUARY 1, 1975.

(A) FOR AMERICIUM-241:

THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS SOURCE, MODEL ___-, SERIAL NO. ___-, ARE SUBJECT TO A GENERAL LICENSE AND THE REGULATIONS OF THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR OF A STATE WITH WHICH THE COMMISSION HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. DO NOT REMOVE THIS LABEL.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

(B) FOR RADIUM:

THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS SOURCE, MODEL ___-, SERIAL NO. ___-, ARE SUBJECT TO A GENERAL LICENSE AND THE REGULATIONS OF A NARM LICENSING STATE. SO NOT REMOVE THIS LABEL.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS RADIUM.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

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Public Health Council

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3701:1-46-39 CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM: LEAK TESTING OF EACH SOURCE.

EACH PERSON LICENSED UNDER RULE 3701:1-46-37 OF THIS CHAPTER SHALL PERFORM A DRY WIPE TEST UPON EACH SOURCE CONTAINING MORE THAN 3.7 KILOBECQURELS (0.1 MICROCURIES) OF AMERICIUM-241 OR RADIUM PRIOR TO TRANSFERRING THE SOURCE TO A GENERAL LICENSEE UNDER RULE 3701:1-46-08 OF THIS CHAPTER. THIS TEST SHALL BE PERFORMED BY WIPING THE ENTIRE RADIOACTIVE SURFACE OF THE SOURCE WITH A FILTER PAPER WITH THE APPLICATION OF MODERATE FINGER PRESSURE. THE RADIOACTIVITY ON THE PAPER SHALL BE MEASURED BY USING RADIATION DETECTION INSTRUMENTATION CAPABLE OF DETECTING ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241 OR RADIUM. IF ANY SUCH TEST DISCLOSES MORE THAN ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIES) OF RADIOACTIVE MATERIAL, THE SOURCE SHALL BE DEEMED TO BE LEAKING OR LOSING AMERICIUM-241 OR RADIUM AND SHALL NOT BE TRANSFERRED TO A GENERAL LICENSEE UNDER RULE 3701:1-46-08 OF THIS CHAPTER.

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3701:1-46-40 ICE DETECTION DEVICES CONTAINING STRONTIUM-90;
REQUIREMENTS FOR LICENSE TO MANUFACTURE OR INITIALLY
TRANSFER.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE OR INITIALLY TRANSFER ICE DETECTION DEVICES CONTAINING STRONTIUM-90 FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-10 OF THIS CHAPTER WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
- (B) THE APPLICANT SUBMITS SUFFICIENT INFORMATION REGARDING EACH TYPE OF DEVICE PERTINENT TO EVALUATION OF THE POTENTIAL RADIATION EXPOSURE, INCLUDING:
 - (1) CHEMICAL AND PHYSICAL FORM AND MAXIMUM QUANTITY OF STRONTIUM-90 IN THE DEVICE;
 - (2) DETAILS OF CONSTRUCTION AND DESIGN OF THE SOURCE OF RADIATION AND ITS SHIELDING;
 - (3) RADIATION PROFILE OF A PROTOTYPE DEVICE;
 - (4) PROCEDURES FOR AND RESULTS OF PROTOTYPE TESTING OF DEVICES TO DEMONSTRATE THAT THE STRONTIUM-90 CONTAINED IN EACH DEVICE WILL NOT BE RELEASED OR BE REMOVED FROM THE DEVICE UNDER THE MOST SEVERE CONDITIONS LIKELY TO BE ENCOUNTERED IN NORMAL HANDLING AND USE;
 - (5) DETAILS OF QUALITY CONTROL PROCEDURES TO BE FOLLOWED IN MANUFACTURE OF THE DEVICE;
 - (6) DESCRIPTION OF LABELING TO BE AFFIXED TO THE DEVICE;
 - (7) INSTRUCTIONS FOR HANDLING AND INSTALLATION OF THE DEVICE;
 - (8) ANY ADDITIONAL INFORMATION, INCLUDING EXPERIMENTAL STUDIES AND TESTS, REQUIRED BY THE DIRECTOR TO FACILITATE A DETERMINATION OF THE SAFETY OF THE DEVICE;
- (C) EACH DEVICE WILL CONTAIN NO MORE THAN 1.85 BECQUERELS (FIFTY MICROCURIES) OF STRONTIUM-90 IN AN INSOLUBLE FORM;
- (D) EACH DEVICE WILL BEAR DURABLE, LEGIBLE LABELING WHICH INCLUDES THE RADIATION SYMBOL PRESCRIBED BY PARAGRAPH (A) OF RULE 3701:1-38-18 OF THE ADMINISTRATIVE CODE, A STATEMENT THAT THE DEVICE CONTAINS STRONTIUM-90 AND THE QUANTITY THEREOF, INSTRUCTIONS FOR DISPOSAL AND STATEMENTS THAT THE DEVICE MAY BE POSSESSED PURSUANT TO A GENERAL LICENSE, THAT THE MANUFACTURER OR CIVIL

AUTHORITIES SHOULD BE NOTIFIED IF THE DEVICE IS FOUND, THAT REMOVAL OF THE LABELING IS PROHIBITED AND THAT DISASSEMBLY AND REPAIR OF THE DEVICE MAY BE PERFORMED ONLY BY A PERSON HOLDING A SPECIFIC LICENSE TO MANUFACTURE OR SERVICE SUCH DEVICES;

(E) THE DIRECTOR DETERMINES THAT:

- (1) THE METHOD OF INCORPORATION AND BINDING OF THE STRONTIUM-90 IN THE DEVICE IS SUCH THAT THE STRONTIUM-90 WILL NOT BE RELEASED FROM THE DEVICE UNDER THE MOST SEVERE CONDITIONS WHICH ARE LIKELY TO BE ENCOUNTERED IN NORMAL USE AND HANDLING OF THE DEVICE;
- (2) THE STRONTIUM-90 IS INCORPORATED OR ENCLOSED SO AS TO PRECLUDE DIRECT PHYSICAL CONTACT BY ANY INDIVIDUAL WITH IT AND IS SHIELDED SO THAT NO INDIVIDUAL WILL RECEIVE A RADIATION EXPOSURE TO A MAJOR PORTION OF HIS BODY IN EXCESS OF FIVE MILLISIEVERTS (0.5 REM) IN A YEAR UNDER ORDINARY CIRCUMSTANCES OF USE;
- (3) THE DEVICE IS SO DESIGNED THAT IT CANNOT BE EASILY DISASSEMBLED;
- (4) THE DEVICE HAS BEEN SUBJECTED TO AND HAS SATISFACTORILY PASSED THE PROTOTYPE TESTS PRESCRIBED BY RULE 3701:1-46-47 OF THIS CHAPTER; AND
- (5) QUALITY CONTROL PROCEDURES HAVE BEEN ESTABLISHED TO SATISFY THE REQUIREMENTS OF RULE 3701:1-46-41 OF THIS CHAPTER.

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3701:1-46-41 ICE DETECTION DEVICES CONTAINING STRONTIUM-90: QUALITY ASSURANCE; PROHIBITION OF TRANSFER.

- (A) EACH PERSON LICENSED UNDER RULE 3701:1-46-40 OF THIS CHAPTER SHALL VISUALLY INSPECT EACH DEVICE AND SHALL REJECT ANY WHICH HAS AN OBSERVABLE PHYSICAL DEFECT THAT COULD AFFECT CONTAINMENT OF THE STRONTIUM-90.
- (B) EACH PERSON LICENSED UNDER RULE 3701:1-46-40 OF THIS CHAPTER SHALL TEST EACH DEVICE FOR POSSIBLE LOSS OF STRONTIUM-90 OR FOR CONTAMINATION BY WIPING WITH FILTER PAPER AN AREA OF AT LEAST ONE HUNDRED SQUARE CENTIMETERS ON THE OUTSIDE SURFACE OF THE DEVICE, OR BY WIPING THE ENTIRE SURFACE AREA IF IT IS LESS THAN ONE HUNDRED SQUARE CENTIMETERS. THE DETECTION ON THE FILTER PAPER OF MORE THAN TWO THOUSAND-TWO HUNDRED DISINTEGRATIONS PER MINUTE OF RADIOACTIVE MATERIAL PER ONE HUNDRED SQUARE CENTIMETERS OF SURFACE WIPED SHALL BE CAUSE FOR REJECTION OF THE TESTED DEVICE.
- (C) EACH PERSON LICENSED UNDER RULE 3701:1-46-40 OF THIS CHAPTER SHALL TAKE A RANDOM SAMPLE OF THE SIZE REQUIRED BY THE TABLE IN RULE 3701:1-46-48 OF THIS CHAPTER FOR LOT TOLERANCE PERCENT DEFECTIVE OF FIVE PERCENT FROM EACH INSPECTION LOT, AND SHALL SUBJECT EACH UNIT IN THE SAMPLE TO THE FOLLOWING TESTS:
 - (1) EACH DEVICE SHALL BE IMMERSSED IN THIRTY INCHES OF WATER FOR TWENTY-FOUR HOURS AND SHALL SHOW NO VISIBLE EVIDENCE OF PHYSICAL CONTACT BETWEEN THE WATER AND THE STRONTIUM-90. ABSOLUTE PRESSURE OF THE AIR ABOVE THE WATER SHALL THEN BE REDUCED TO ONE INCH OF MERCURY. LOWERED PRESSURE SHALL BE MAINTAINED FOR ONE MINUTE OR UNTIL AIR BUBBLES CEASE TO BE GIVEN OFF BY THE WATER, WHICHEVER IS THE LONGER. PRESSURE SHALL THEN BE INCREASED TO NORMAL ATMOSPHERIC PRESSURE. ANY DEVICE THAT LEAKS, AS EVIDENCED BY PHYSICAL CONTACT BETWEEN THE WATER AND THE STRONTIUM-90, SHALL BE CONSIDERED AS A DEFECTIVE UNIT.
 - (2) THE IMMERSION TEST WATER FROM THE PRECEDING TEST IN PARAGRAPH (C)(1) OF THIS RULE SHALL BE MEASURED FOR RADIOACTIVE MATERIAL. IF THE AMOUNT OF RADIOACTIVE MATERIAL IN THE IMMERSION TEST WATER IS GREATER THAN 0.1 PERCENT OF THE ORIGINAL AMOUNT OF STRONTIUM-90 IN ANY DEVICE, THE DEVICE SHALL BE CONSIDERED AS A DEFECTIVE UNIT.
- (D) AN APPLICATION FOR A LICENSE OR FOR AMENDMENT OF A LICENSE MAY INCLUDE A DESCRIPTION OF PROCEDURES PROPOSED AS ALTERNATIVES TO THOSE PRESCRIBED BY PARAGRAPH (C) OF THIS RULE, AND PROPOSED CRITERIA FOR ACCEPTANCE UNDER THOSE PROCEDURES. THE DIRECTOR WILL APPROVE THE PROPOSED ALTERNATIVE PROCEDURES IF THE APPLICANT DEMONSTRATES THAT:

- (1) THEY WILL CONSIDER DEFECTIVE ANY SAMPLED DEVICE WHICH HAS A LEAKAGE RATE EXCEEDING 0.1 PERCENT OF THE ORIGINAL QUANTITY OF STRONTIUM-90 IN ANY TWENTY-FOUR HOUR PERIOD; AND
 - (2) THE OPERATING CHARACTERISTIC CURVE OR CONFIDENCE INTERVAL ESTIMATE FOR THE ALTERNATIVE PROCEDURES PROVIDES A LOT TOLERANCE PERCENT DEFECTIVE OF FIVE PERCENT AT THE CONSUMER'S RISK OF 0.1.
- (E) NO PERSON LICENSED UNDER RULE 3701:1-46-40 OF THIS CHAPTER SHALL TRANSFER TO PERSONS GENERALLY LICENSED UNDER RULE 3701:1-46-10 OF THIS CHAPTER:
- (1) ANY DEVICE WHICH HAS BEEN TESTED AND FOUND DEFECTIVE UNDER THE CRITERIA AND PROCEDURES SPECIFIED IN THIS RULE UNLESS THE DEFECTIVE UNITS HAVE BEEN REPAIRED OR REWORKED AND THEN MET THE TESTS SET OUT IN PARAGRAPH (C) OF THIS RULE; OR
 - (2) ANY INSPECTION LOT WHICH HAS BEEN REJECTED AS A RESULT OF THE PROCEDURES IN RULE 3701:1-46-48 OF THIS CHAPTER OR ALTERNATIVE PROCEDURES IN PARAGRAPH (D) OF THIS RULE, UNLESS THE DEFECTIVE UNITS HAVE BEEN SORTED AND REMOVED OR HAVE BEEN REPAIRED OR REWORKED AND HAVE THEN MET THE TESTS SET OUT IN PARAGRAPH (C) OF THIS RULE.

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3701:1-46-42 MANUFACTURE AND DISTRIBUTION OF BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL FOR CERTAIN IN VITRO CLINICAL OR LABORATORY TESTING UNDER GENERAL LICENSE.

AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE OR DISTRIBUTE BYPRODUCT AND ACCELERATOR PRODUCED MATERIAL FOR USE UNDER THE GENERAL LICENSE IN RULE 3701:1-46-11 OF THIS CHAPTER WILL BE APPROVED IF:

- (A) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE.
- (B) THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL IS TO BE PREPARED FOR DISTRIBUTION IN PREPACKAGED UNITS OF:
 - (1) IODINE-125 IN UNITS NOT EXCEEDING THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH.
 - (2) IODINE-131 IN UNITS NOT EXCEEDING THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH.
 - (3) CARBON-14 IN UNITS NOT EXCEEDING THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH.
 - (4) HYDROGEN-3 (TRITIUM) IN UNITS NOT EXCEEDING 1.85 MEGABECQUERELS (FIFTY MICROCURIES) EACH.
 - (5) IRON-59 IN UNITS NOT EXCEEDING SEVEN HUNDRED FORTY KILOBECQUERELS (TWENTY MICROCURIES) EACH.
 - (6) SELENIUM-75 IN UNITS NOT EXCEEDING THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH.
 - (7) MOCK IODINE-125 IN UNITS NOT EXCEEDING 1.85 KILOBECQUERELS (0.05 MICROCURIES) OF IODINE-129 AND ONE HUNDRED EIGHTY FIVE BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241 EACH.
 - (8) COBALT-57 IN UNITS NOT EXCEEDING THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) EACH.
- (C) EACH PREPACKAGED UNIT BEARS A DURABLE, CLEARLY VISIBLE LABEL:
 - (1) IDENTIFYING THE RADIOACTIVE CONTENTS AS TO CHEMICAL FORM AND RADIONUCLIDE, AND INDICATING THAT THE AMOUNT OF RADIOACTIVITY DOES NOT EXCEED THREE HUNDRED SEVENTY KILOBECQUERELS (TEN MICROCURIES) OF IODINE-131, IODINE-125, SELENIUM-75, COBALT-57, OR CARBON-14; 1.85 MEGABECQUERELS (FIFTY MICROCURIES) OF HYDROGEN-3 (TRITIUM); OR SEVEN HUNDRED FORTY KILOBECQUERELS (TWENTY MICROCURIES) OF IRON-59; OR MOCK IODINE-125 IN UNITS NOT EXCEEDING 1.85 KILOBECQUERELS (0.05 MICROCURIES) OF IODINE-129 AND 1.85 BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241 EACH; AND

- (2) DISPLAYING THE RADIATION SYMBOL DESCRIBED IN PARAGRAPH (A) OF RULE 3701:1-38-18 OF THE ADMINISTRATIVE CODE AND THE WORDS, "CAUTION, RADIOACTIVE MATERIAL", AND "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS."
- (D) THE FOLLOWING STATEMENT, OR A SUBSTANTIALLY SIMILAR STATEMENT WHICH CONTAINS THE INFORMATION CALLED FOR IN THE FOLLOWING STATEMENT, APPEARS ON A LABEL AFFIXED TO EACH PREPACKAGED UNIT OR APPEARS IN A LEAFLET OR BROCHURE WHICH ACCOMPANIES THE PACKAGE:

- (1) FOR BYPRODUCT MATERIAL:

THE RADIOACTIVE MATERIAL MAY BE RECEIVED, ACQUIRED, POSSESSED, AND USED ONLY BY PHYSICIANS, VETERINARIANS IN THE PRACTICE OF VETERINARY MEDICINE, CLINICAL LABORATORIES OR HOSPITALS AND ONLY FOR IN VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF THE MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS. ITS RECEIPT, ACQUISITION, POSSESSION, USE, AND TRANSFER ARE SUBJECT TO THE REGULATIONS AND A GENERAL LICENSE OF THE U.S. NUCLEAR REGULATORY COMMISSION OR OF A STATE WITH WHICH THE COMMISSION HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY.

(NAME OF MANUFACTURER)

- (2) FOR ACCELERATOR PRODUCED MATERIAL:

THE RADIOACTIVE MATERIAL MAY BE RECEIVED, ACQUIRED, POSSESSED, AND USED ONLY BY PHYSICIANS, VETERINARIANS IN THE PRACTICE OF VETERINARY MEDICINE, CLINICAL LABORATORIES OR HOSPITALS AND ONLY FOR IN VITRO CLINICAL OR LABORATORY TESTS NOT INVOLVING INTERNAL OR EXTERNAL ADMINISTRATION OF THE MATERIAL, OR THE RADIATION THEREFROM, TO HUMAN BEINGS OR ANIMALS. ITS RECEIPT, ACQUISITION, POSSESSION, USE, AND TRANSFER ARE SUBJECT TO THE REGULATIONS AND A GENERAL LICENSE OF A NARM LICENSING STATE.

(NAME OF MANUFACTURER)

- (E) THE LABEL AFFIXED TO THE UNIT, OR THE LEAFLET OR BROCHURE WHICH ACCOMPANIES THE PACKAGE, CONTAINS ADEQUATE INFORMATION AS TO THE PRECAUTIONS TO BE OBSERVED IN HANDLING AND STORING SUCH BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL. IN THE CASE OF THE MOCK IODINE-125 REFERENCE OR CALIBRATION SOURCE, THE INFORMATION ACCOMPANYING THE SOURCE MUST ALSO CONTAIN DIRECTIONS TO THE LICENSEE REGARDING THE WASTE DISPOSAL

REQUIREMENTS SET OUT IN PARAGRAPH (A) OF RULE 3701:1-38-19 OF THE
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3701:1-46-43 MANUFACTURE, PREPARATION, OR TRANSFER FOR COMMERCIAL DISTRIBUTION OF RADIOACTIVE DRUGS CONTAINING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL FOR MEDICAL USE UNDER 10 CFR 35.

- (A) AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE, PREPARE, OR TRANSFER FOR COMMERCIAL DISTRIBUTION RADIOACTIVE DRUGS CONTAINING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL FOR USE BY PERSONS AUTHORIZED PURSUANT TO 10 C.F.R. 35 OR EQUIVALENT REGULATIONS OF AN AGREEMENT STATE OR NARM LICENSING STATE WILL BE APPROVED IF:
- (1) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS SPECIFIED IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
 - (2) THE APPLICANT SUBMITS EVIDENCE THAT THE APPLICANT IS AT LEAST ONE OF THE FOLLOWING:
 - (a) REGISTERED OR LICENSED WITH THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) AS A DRUG MANUFACTURER;
 - (b) REGISTERED OR LICENSED WITH A STATE AGENCY AS A DRUG MANUFACTURER;
 - (c) LICENSED AS A PHARMACY BY A STATE BOARD OF PHARMACY; OR
 - (d) OPERATING AS A NUCLEAR PHARMACY WITHIN A FEDERAL MEDICAL INSTITUTION.
 - (3) THE APPLICANT SUBMITS INFORMATION ON THE RADIONUCLIDE; THE CHEMICAL AND PHYSICAL FORM; THE MAXIMUM ACTIVITY PER VIAL, SYRINGE, GENERATOR, OR OTHER CONTAINER OF THE RADIOACTIVE DRUG; AND THE SHIELDING PROVIDED BY THE PACKAGING TO SHOW IT IS APPROPRIATE FOR THE SAFE HANDLING AND STORAGE OF THE RADIOACTIVE DRUGS BY MEDICAL USE LICENSEES; AND
 - (4) THE APPLICANT SATISFIES THE FOLLOWING LABELING REQUIREMENTS:
 - (a) A LABEL IS AFFIXED TO EACH TRANSPORT RADIATION SHIELD, WHETHER IT IS CONSTRUCTED OF LEAD, GLASS, PLASTIC, OR OTHER MATERIAL, OF A RADIOACTIVE DRUG TO BE TRANSFERRED FOR COMMERCIAL DISTRIBUTION. THE LABEL MUST INCLUDE THE RADIATION SYMBOL AND THE WORDS "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL"; THE NAME OF THE RADIOACTIVE DRUG OR ITS ABBREVIATION; AND THE QUANTITY OF RADIOACTIVITY AT A SPECIFIED DATE AND TIME. FOR RADIOACTIVE DRUGS WITH A HALF LIFE GREATER THAN ONE HUNDRED DAYS, THE TIME MAY BE OMITTED.

- (b) A LABEL IS AFFIXED TO EACH SYRINGE, VIAL, OR OTHER CONTAINER USED TO HOLD A RADIOACTIVE DRUG TO BE TRANSFERRED FOR COMMERCIAL DISTRIBUTION. THE LABEL MUST INCLUDE THE RADIATION SYMBOL AND THE WORDS "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL" AND AN IDENTIFIER THAT ENSURES THAT THE SYRINGE, VIAL, OR OTHER CONTAINER CAN BE CORRELATED WITH THE INFORMATION ON THE TRANSPORT RADIATION SHIELD LABEL.
- (B) A LICENSEE DESCRIBED BY PARAGRAPH (A)(2)(c) OR (d) OF THIS RULE:
- (1) MAY PREPARE RADIOACTIVE DRUGS FOR MEDICAL USE, AS DEFINED IN 10 CFR 35.2, PROVIDED THAT THE RADIOACTIVE DRUG IS PREPARED BY EITHER AN AUTHORIZED NUCLEAR PHARMACIST, AS SPECIFIED IN PARAGRAPH (B)(2) AND (B)(3) OF THIS RULE, OR AN INDIVIDUAL UNDER THE SUPERVISION OF AN AUTHORIZED NUCLEAR PHARMACIST AS SPECIFIED IN 10 CFR 35.25.
 - (2) MAY ALLOW A PHARMACIST TO WORK AS AN AUTHORIZED NUCLEAR PHARMACIST IF:
 - (a) THIS INDIVIDUAL QUALIFIES AS AN AUTHORIZED NUCLEAR PHARMACIST AS DEFINED IN 10 CFR 35.2,
 - (b) THIS INDIVIDUAL MEETS THE REQUIREMENTS SPECIFIED IN 10 CFR 35.980(b) AND 10 CFR 35.972 AND THE LICENSEE HAS RECEIVED AN APPROVED LICENSE AMENDMENT IDENTIFYING THIS INDIVIDUAL AS AN AUTHORIZED NUCLEAR PHARMACIST, OR
 - (c) THIS INDIVIDUAL IS DESIGNATED AS AN AUTHORIZED NUCLEAR PHARMACIST IN ACCORDANCE WITH PARAGRAPH (B)(3) OF THIS RULE.
 - (3) THE ACTIONS AUTHORIZED IN PARAGRAPHS (B)(1) AND (B)(2) OF THIS RULE ARE PERMITTED IN SPITE OF MORE RESTRICTIVE LANGUAGE IN LICENSE CONDITIONS.
 - (4) MAY DESIGNATE A PHARMACIST (AS DEFINED IN 10 CFR 35.2) AS AN AUTHORIZED NUCLEAR PHARMACIST IF THE INDIVIDUAL IS IDENTIFIED AS OF DECEMBER 2, 1994, AS AN "AUTHORIZED USER" ON A NUCLEAR PHARMACY LICENSE ISSUED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE.
 - (5) SHALL PROVIDE TO THE DIRECTOR A COPY OF EACH INDIVIDUAL'S CERTIFICATION BY THE BOARD OF PHARMACEUTICAL SPECIALTIES, THE OHIO, UNITED STATES NUCLEAR REGULATORY COMMISSION, OR AGREEMENT STATE OR NARM LICENSING STATE LICENSE, OR THE PERMIT ISSUED BY A LICENSEE OF BROAD SCOPE, AND A COPY OF

THE STATE PHARMACY LICENSURE OR REGISTRATION, NO LATER THAN THIRTY DAYS AFTER THE DATE THAT THE LICENSEE ALLOWS, PURSUANT TO PARAGRAPHS (B)(2)(a) AND (B)(2)(c) OF THIS RULE, THE INDIVIDUAL TO WORK AS AN AUTHORIZED NUCLEAR PHARMACIST.

- (C) A LICENSEE SHALL POSSESS AND USE INSTRUMENTATION TO MEASURE THE RADIOACTIVITY OF RADIOACTIVE DRUGS. THE LICENSEE SHALL HAVE PROCEDURES FOR USE OF THE INSTRUMENTATION. THE LICENSEE SHALL MEASURE, BY DIRECT MEASUREMENT OR BY COMBINATION OF MEASUREMENTS AND CALCULATIONS, THE AMOUNT OF RADIOACTIVITY IN DOSAGES OF ALPHA-, BETA-, OR PHOTON-EMITTING RADIOACTIVE DRUGS PRIOR TO TRANSFER FOR COMMERCIAL DISTRIBUTION. IN ADDITION, THE LICENSEE SHALL:
 - (1) PERFORM TESTS BEFORE INITIAL USE, PERIODICALLY, AND FOLLOWING REPAIR, ON EACH INSTRUMENT FOR ACCURACY, LINEARITY, AND GEOMETRY DEPENDENCE, AS APPROPRIATE FOR THE USE OF THE INSTRUMENT; AND MAKE ADJUSTMENTS WHEN NECESSARY; AND
 - (2) CHECK EACH INSTRUMENT FOR CONSTANCY AND PROPER OPERATION AT THE BEGINNING OF EACH DAY OF USE.
- (D) NOTHING IN THIS RULE RELIEVES THE LICENSEE FROM COMPLYING WITH APPLICABLE FDA, OTHER FEDERAL, AND STATE REQUIREMENTS GOVERNING RADIOACTIVE DRUGS.

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3701:1-46-44 MANUFACTURE AND DISTRIBUTION OF SOURCES OR DEVICES CONTAINING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL FOR MEDICAL USE.

- (A) AN APPLICATION FOR A SPECIFIC LICENSE TO MANUFACTURE AND DISTRIBUTE SOURCES AND DEVICES CONTAINING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL TO PERSONS LICENSED PURSUANT TO 10 C.F.R. 35 OR EQUIVALENT AGREEMENT STATE OR NARM LICENSING STATE REGULATIONS FOR USE AS A CALIBRATION OR REFERENCE SOURCE OR FOR THE USES LISTED IN 10 C.F.R. 35.400 AND 10 C.F.R. 35.500 OR EQUIVALENT AGREEMENT STATE OR NARM LICENSING STATE REGULATIONS WILL BE APPROVED IF:
- (1) THE APPLICANT SATISFIES THE GENERAL REQUIREMENTS IN RULE 3701:1-40-15 OF THE ADMINISTRATIVE CODE;
 - (2) THE APPLICANT SUBMITS SUFFICIENT INFORMATION REGARDING EACH TYPE OF SOURCE OR DEVICE PERTINENT TO AN EVALUATION OF ITS RADIATION SAFETY, INCLUDING:
 - (a) THE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL CONTAINED, ITS CHEMICAL AND PHYSICAL FORM, AND AMOUNT;
 - (b) DETAILS OF DESIGN AND CONSTRUCTION OF THE SOURCE OR DEVICE;
 - (c) PROCEDURES FOR, AND RESULTS OF, PROTOTYPE TESTS TO DEMONSTRATE THAT THE SOURCE OR DEVICE WILL MAINTAIN ITS INTEGRITY UNDER STRESSES LIKELY TO BE ENCOUNTERED IN NORMAL USE AND ACCIDENTS;
 - (d) FOR DEVICES CONTAINING BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL, THE RADIATION PROFILE OF A PROTOTYPE DEVICE;
 - (e) DETAILS OF QUALITY CONTROL PROCEDURES TO ASSURE THAT PRODUCTION SOURCES AND DEVICES MEET THE STANDARDS OF THE DESIGN AND PROTOTYPE TESTS;
 - (f) PROCEDURES AND STANDARDS FOR CALIBRATING SOURCES AND DEVICES;
 - (g) LEGEND AND METHODS FOR LABELING SOURCES AND DEVICES AS TO THEIR RADIOACTIVE CONTENT;
 - (h) INSTRUCTIONS FOR HANDLING AND STORING THE SOURCE OR DEVICE FROM THE RADIATION SAFETY STANDPOINT; THESE INSTRUCTIONS ARE TO BE INCLUDED ON A DURABLE LABEL ATTACHED TO THE SOURCE OR DEVICE OR ATTACHED

TO A PERMANENT STORAGE CONTAINER FOR THE SOURCE OR DEVICE: PROVIDED, THAT INSTRUCTIONS WHICH ARE TOO LENGTHY FOR SUCH LABEL MAY BE SUMMARIZED ON THE LABEL AND PRINTED IN DETAIL ON A BROCHURE WHICH IS REFERENCED ON THE LABEL;

- (3) THE LABEL AFFIXED TO THE SOURCE OR DEVICE, OR TO THE PERMANENT STORAGE CONTAINER FOR THE SOURCE OR DEVICE, CONTAINS INFORMATION ON THE RADIONUCLIDE, QUANTITY AND DATE OF ASSAY, AND A STATEMENT THAT THE DIRECTOR HAS APPROVED DISTRIBUTION OF THE (NAME OF SOURCE OR DEVICE) TO PERSONS LICENSED TO USE BYPRODUCT OR ACCELERATOR PRODUCED MATERIAL IDENTIFIED IN 10 CFR 35.57, 10 CFR 35.400, 10 CFR 35.500, AS APPROPRIATE, AND TO PERSONS WHO HOLD AN EQUIVALENT LICENSE ISSUED BY THE NUCLEAR REGULATORY COMMISSION OR AN AGREEMENT STATE OR NARM LICENSING STATE.
- (B) THE FOLLOWING IS APPLICABLE:
- (1) IN THE EVENT THE APPLICANT DESIRES THAT THE SOURCE OR DEVICE BE REQUIRED TO BE TESTED FOR LEAKAGE OF RADIOACTIVE MATERIAL AT INTERVALS LONGER THAN SIX MONTHS, HE/SHE SHALL INCLUDE IN HIS/HER APPLICATION SUFFICIENT INFORMATION TO DEMONSTRATE THAT SUCH LONGER INTERVAL IS JUSTIFIED BY PERFORMANCE CHARACTERISTICS OF THE SOURCE OR DEVICE OR SIMILAR SOURCES OR DEVICES AND BY DESIGN FEATURES THAT HAVE A SIGNIFICANT BEARING ON THE PROBABILITY OR CONSEQUENCES OF LEAKAGE OF RADIOACTIVE MATERIAL FROM THE SOURCE.
 - (2) IN DETERMINING THE ACCEPTABLE INTERVAL FOR TEST OF LEAKAGE OF RADIOACTIVE MATERIAL, THE DIRECTOR WILL CONSIDER INFORMATION THAT INCLUDES, BUT IS NOT LIMITED TO:
 - (a) PRIMARY CONTAINMENT (SOURCE CAPSULE);
 - (b) PROTECTION OF PRIMARY CONTAINMENT;
 - (c) METHOD OF SEALING CONTAINMENT;
 - (d) CONTAINMENT CONSTRUCTION MATERIALS;
 - (e) FORM OF CONTAINED RADIOACTIVE MATERIAL;
 - (f) MAXIMUM TEMPERATURE WITHSTOOD DURING PROTOTYPE TESTS;
 - (g) MAXIMUM PRESSURE WITHSTOOD DURING PROTOTYPE TESTS;
 - (h) MAXIMUM QUANTITY OF CONTAINED RADIOACTIVE MATERIAL;

- (i) RADIOTOXICITY OF CONTAINED RADIOACTIVE MATERIAL;
- (j) OPERATING EXPERIENCE WITH IDENTICAL SOURCES OR DEVICES OR SIMILARLY DESIGNED AND CONSTRUCTED SOURCES OR DEVICES.

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3701:1-46-45 PROTOTYPE TESTS FOR LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT.

AN APPLICANT FOR A LICENSE PURSUANT TO RULE 3701:1-46-33 OF THIS CHAPTER SHALL CONDUCT PROTOTYPE TESTS ON EACH OF FIVE PROTOTYPE LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT AS FOLLOWS:

- (A) TEMPERATURE-ALTITUDE TEST. THE DEVICE SHALL BE PLACED IN A TEST CHAMBER AS IT WOULD BE USED IN SERVICE. A TEMPERATURE-ALTITUDE CONDITION SCHEDULE SHALL BE FOLLOWED AS OUTLINED IN TABLE 1:

TABLE 1 TEMPERATURE-ALTITUDE TEST	
STEP 1	THE INTERNAL TEMPERATURE OF THE TEST CHAMBER SHALL BE REDUCED TO MINUS SIXTY-TWO DEGREES CELSIUS (EIGHTY DEGREES FAHRENHEIT) AND THE DEVICE SHALL BE MAINTAINED FOR AT LEAST ONE HOUR AT THIS TEMPERATURE AT ATMOSPHERIC PRESSURE.
STEP 2	THE INTERNAL TEMPERATURE OF THE TEST CHAMBER SHALL BE RAISED TO MINUS FIFTY-FOUR DEGREES CELSIUS (MINUS SIXTY-FIVE DEGREES FAHRENHEIT) AND MAINTAINED UNTIL THE TEMPERATURE OF THE DEVICE HAS STABILIZED AT MINUS FIFTY-FOUR DEGREES CELSIUS AT ATMOSPHERIC PRESSURE.
STEP 3	THE ATMOSPHERIC PRESSURE OF THE CHAMBER SHALL BE REDUCED TO EIGHTY-THREE MILLIMETERS OF MERCURY ABSOLUTE PRESSURE WHILE THE CHAMBER TEMPERATURE IS MAINTAINED AT MINUS FIFTY-FOUR DEGREES CELSIUS.
STEP 4	THE INTERNAL TEMPERATURE OF THE CHAMBER SHALL BE RAISED TO MINUS TEN DEGREES CELSIUS (FOURTEEN DEGREES FAHRENHEIT) AND MAINTAINED UNTIL THE TEMPERATURE OF THE DEVICE HAS STABILIZED AT TEN DEGREES CELSIUS, AND THE INTERNAL PRESSURE OF THE CHAMBER SHALL THEN BE ADJUSTED TO ATMOSPHERIC PRESSURE. THE TEST CHAMBER DOOR SHALL THEN BE OPENED IN ORDER THAT FROST WILL FORM ON THE DEVICE, AND SHALL REMAIN OPEN UNTIL THE FROST HAS MELTED BUT NOT LONG ENOUGH TO ALLOW THE MOISTURE TO EVAPORATE. THE DOOR SHALL THEN BE CLOSED.
STEP 5	THE INTERNAL TEMPERATURE OF THE CHAMBER SHALL BE RAISED TO EIGHTY-FIVE DEGREES CELSIUS (ONE HUNDRED EIGHTY-FIVE DEGREES FAHRENHEIT) AT ATMOSPHERIC PRESSURE. THE TEMPERATURE OF THE DEVICE SHALL BE STABILIZED AT EIGHTY-FIVE DEGREES CELSIUS AND

	MAINTAINED FOR TWO HOURS. THE DEVICE SHALL THEN BE VISUALLY INSPECTED TO DETERMINE THE EXTENT OF ANY DETERIORATION.
STEP 6	THE CHAMBER TEMPERATURE SHALL BE REDUCED TO SEVENTY-ONE DEGREES CELSIUS (ONE HUNDRED SIXTY DEGREES FAHRENHEIT) AT ATMOSPHERIC PRESSURE. THE TEMPERATURE OF THE DEVICE SHALL BE STABILIZED AT SEVENTY-ONE DEGREES CELSIUS FOR A PERIOD OF THIRTY MINUTES.
STEP 7	THE CHAMBER TEMPERATURE SHALL BE REDUCED TO FIFTY-FIVE DEGREES CELSIUS (ONE HUNDRED THIRTY DEGREES FAHRENHEIT) AT ATMOSPHERIC PRESSURE. THE TEMPERATURE OF THE DEVICE SHALL BE STABILIZED AT THIS TEMPERATURE FOR A PERIOD OF FOUR HOURS.
STEP 8	THE INTERNAL TEMPERATURE OF THE CHAMBER SHALL BE REDUCED TO THIRTY DEGREES CELSIUS (EIGHTY-SIX DEGREES FAHRENHEIT) AND THE PRESSURE TO ONE HUNDRED THIRTY-EIGHT MILLIMETERS OF MERCURY ABSOLUTE PRESSURE AND STABILIZED. THE DEVICE SHALL BE MAINTAINED UNDER THESE CONDITIONS FOR A PERIOD OF FOUR HOURS.
STEP 9	THE TEMPERATURE OF THE TEST CHAMBER SHALL BE RAISED TO THIRTY-FIVE DEGREES CELSIUS. (NINETY-FIVE DEGREES FAHRENHEIT) AND THE PRESSURE REDUCED TO EIGHTY-THREE MILLIMETERS OF MERCURY ABSOLUTE PRESSURE AND STABILIZED. THE DEVICE SHALL BE MAINTAINED UNDER THESE CONDITIONS FOR A PERIOD OF THIRTY MINUTES.
STEP 10	THE INTERNAL PRESSURE OF THE CHAMBER SHALL BE MAINTAINED AT EIGHTY-THREE MILLIMETERS OF MERCURY ABSOLUTE PRESSURE AND THE TEMPERATURE REDUCED TO TWENTY DEGREES CELSIUS. (SIXTY-EIGHT DEGREES FAHRENHEIT) AND STABILIZED. THE DEVICE SHALL BE MAINTAINED UNDER THESE CONDITIONS FOR A PERIOD OF FOUR HOURS.

- (B) VIBRATION TESTS. THIS PROCEDURE APPLIES TO ITEMS OF EQUIPMENT (INCLUDING VIBRATION ISOLATING ASSEMBLIES) INTENDED TO BE MOUNTED DIRECTLY ON THE STRUCTURE OF AIRCRAFT POWERED BY RECIPROCATING, TURBOJET, OR TURBO-PROPELLER ENGINES OR TO BE MOUNTED DIRECTLY ON GAS-TURBINE ENGINES. THE DEVICE SHALL BE MOUNTED ON AN APPARATUS DYNAMICALLY SIMILAR TO THE MOST SEVERE CONDITIONS LIKELY TO BE ENCOUNTERED IN NORMAL USE. AT THE END OF THE TEST PERIOD, THE DEVICE SHALL BE INSPECTED THOROUGHLY FOR POSSIBLE DAMAGE. VIBRATION TESTS SHALL BE CONDUCTED UNDER BOTH

RESONANT AND CYCLING CONDITIONS ACCORDING TO THE FOLLOWING
VIBRATION TEST SCHEDULE (TABLE 2)

<u>VIBRATION TEST SCHEDULE-TABLE 2</u>			
<u>[TIMES SHOWN REFER TO ONE AXIS OF VIBRATION]</u>			
<u>TYPE</u>	<u>VIBRATION AT ROOM TEMPERATURE (MINUTES)</u>	<u>VIBRATION AT 160° F (71° C.) (MINUTES)</u>	<u>VIBRATION AT -65° F (-54° C.) (MINUTES)</u>
<u>RESONANCE</u>	60	15	15
<u>CYCLING</u>	60	15	15

- (1) DETERMINATION OF RESONANCE FREQUENCY. INDIVIDUAL RESONANCE FREQUENCY SURVEYS SHALL BE CONDUCTED BY APPLYING VIBRATION TO EACH DEVICE ALONG EACH OF ANY SET OF THREE MUTUALLY PERPENDICULAR AXES AND VARYING THE FREQUENCY OF APPLIED VIBRATION SLOWLY THROUGH A RANGE OF FREQUENCIES FROM FIVE CYCLES PER SECOND TO FIVE HUNDRED CYCLES PER SECOND WITH THE DOUBLE AMPLITUDE OF THE VIBRATION NOT EXCEEDING THAT SHOWN IN FIGURE 1 FOR THE RELATED FREQUENCY.
- (2) RESONANCE TESTS. THE DEVICE SHALL BE VIBRATED AT THE DETERMINED RESONANCE FREQUENCY FOR EACH AXIS OF VIBRATION FOR THE PERIODS AND TEMPERATURE CONDITIONS SHOWN IN TABLE 1 AND WITH THE APPLIED DOUBLE AMPLITUDE SPECIFIED IN FIGURE 1 FOR THAT RESONANCE FREQUENCY. WHEN MORE THAN ONE RESONANT FREQUENCY IS ENCOUNTERED WITH VIBRATION APPLIED ALONG ANY ONE AXIS, THE TEST PERIOD MAY BE ACCOMPLISHED AT THE MOST SEVERE RESONANCE OR THE PERIOD MAY BE DIVIDED AMONG THE RESONANT FREQUENCIES, WHICHEVER IS CONSIDERED MOST LIKELY TO PRODUCE FAILURE. WHEN RESONANT FREQUENCIES ARE NOT APPARENT WITHIN THE SPECIFIED FREQUENCY RANGE, THE SPECIMEN SHALL BE VIBRATED FOR PERIODS TWICE AS LONG AS THOSE SHOWN FOR RESONANCE IN TABLE 2 AT A FREQUENCY OF FIFTY-FIVE CYCLES PER SECOND AND AN APPLIED DOUBLE AMPLITUDE OF 0.060 INCH.
- (3) CYCLING. DEVICES TO BE MOUNTED ONLY ON VIBRATION ISOLATORS SHALL BE TESTED BY APPLYING VIBRATION ALONG EACH OF THREE MUTUALLY PERPENDICULAR AXES OF THE DEVICE WITH AN APPLIED DOUBLE AMPLITUDE OF 0.060 INCH AND THE FREQUENCY CYCLING BETWEEN TEN AND FIFTY-FIVE CYCLES PER SECOND IN ONE MINUTE CYCLES FOR THE PERIODS AND TEMPERATURE CONDITIONS SHOWN IN TABLE 2. DEVICES TO BE INSTALLED IN AIRCRAFT WITHOUT VIBRATION ISOLATORS SHALL BE TESTED BY APPLYING VIBRATION ALONG EACH OF THREE MUTUALLY PERPENDICULAR AXES OF THE DEVICE WITH AN APPLIED DOUBLE AMPLITUDE OF 0.036 INCH OR AN APPLIED ACCELERATION OF TEN G, WHICHEVER IS THE LIMITING VALUE, AND THE FREQUENCY CYCLING

BETWEEN TEN AND FIVE HUNDRED CYCLES PER SECOND IN FIFTEEN MINUTE CYCLES FOR THE PERIODS AND TEMPERATURE CONDITIONS SHOWN IN TABLE 2.

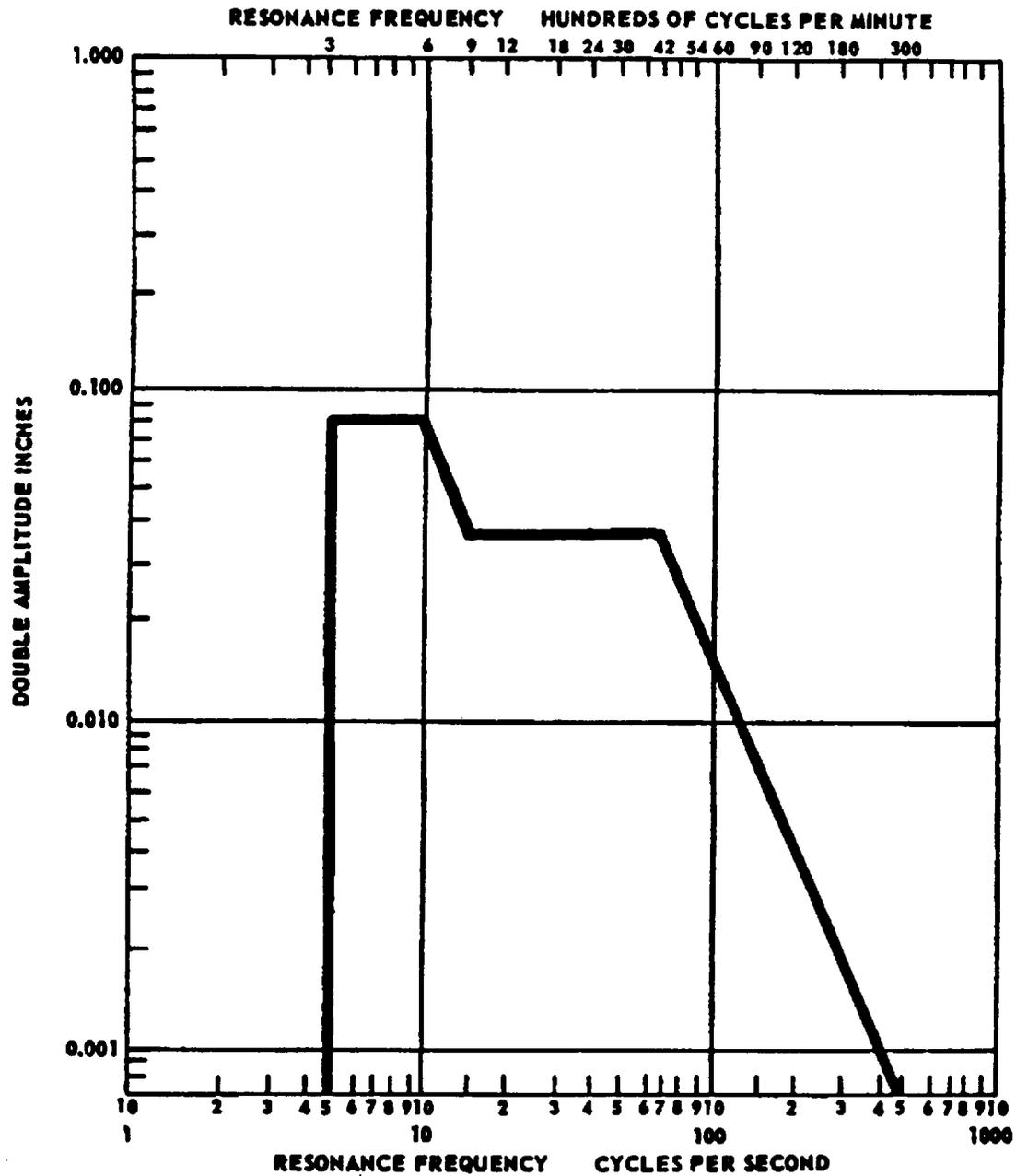


FIGURE 1—Amplitude of vibration at resonance frequency.

- (C) ACCELERATED WEATHERING TESTS. THE DEVICE SHALL BE SUBJECTED TO ONE HUNDRED HOURS OF ACCELERATED WEATHERING IN A SUITABLE WEATHERING MACHINE. PANELS OF COREX D GLASS SHALL SURROUND THE

ARC TO CUT OFF THE ULTRAVIOLET RADIATION BELOW A WAVE LENGTH OF TWO THOUSAND SEVEN HUNDRED ANGSTROMS. THE LIGHT OF THE CARBON ARCS SHALL FALL DIRECTLY ON THE FACE OF THE DEVICE. THE TEMPERATURE AT THE SAMPLE SHALL BE MAINTAINED AT FIFTY DEGREES CELSIUS PLUS OR MINUS THREE DEGREES CELSIUS. TEMPERATURE MEASUREMENTS SHALL BE MADE WITH A BLACK PANEL THERMOMETER.

- (D) SHOCK TEST. THE DEVICE SHALL BE DROPPED UPON A CONCRETE OR IRON SURFACE IN A THREE FOOT FREE GRAVITATIONAL FALL, OR SHALL BE SUBJECTED TO EQUIVALENT TREATMENT IN A TEST DEVICE SIMULATING SUCH A FREE FALL. THE DROP TEST SHALL BE REPEATED ONE HUNDRED TIMES FROM RANDOM ORIENTATIONS.
- (E) HERMETIC SEAL AND WATERPROOF TEST. ON COMPLETION OF ALL OTHER TESTS PRESCRIBED BY THIS SECTION, THE DEVICE SHALL BE IMMERSSED IN THIRTY INCHES OF WATER FOR TWENTY-FOUR HOURS AND SHALL SHOW NO VISIBLE EVIDENCE OF WATER ENTRY. ABSOLUTE PRESSURE OF THE AIR ABOVE THE WATER SHALL THEN BE REDUCED TO ONE INCH OF MERCURY. LOWERED PRESSURE SHALL BE MAINTAINED FOR ONE MINUTE OR UNTIL AIR BUBBLES CEASE TO BE GIVEN OFF BY THE WATER, WHICHEVER IS THE LONGER. PRESSURE SHALL THEN BE INCREASED TO NORMAL ATMOSPHERIC PRESSURE. ANY EVIDENCE OF BUBBLES EMANATING FROM WITHIN THE DEVICE, OR WATER ENTERING THE DEVICE, SHALL BE CONSIDERED LEAKAGE.
- (F) OBSERVATIONS. AFTER EACH OF THE TESTS PRESCRIBED BY THIS SECTION, EACH DEVICE SHALL BE EXAMINED FOR EVIDENCE OF PHYSICAL DAMAGE AND FOR LOSS OF TRITIUM OR PROMETHIUM-147. ANY EVIDENCE OF DAMAGE TO OR FAILURE OF ANY DEVICE WHICH COULD AFFECT CONTAINMENT OF THE TRITIUM OR PROMETHIUM-147 SHALL BE CAUSE FOR REJECTION OF THE DESIGN IF THE DAMAGE OR FAILURE IS ATTRIBUTABLE TO A DESIGN DEFECT. LOSS OF TRITIUM OR PROMETHIUM-147 FROM EACH TESTED DEVICE SHALL BE MEASURED BY WIPING WITH FILTER PAPER AN AREA OF AT LEAST ONE HUNDRED SQUARE CENTIMETERS ON THE OUTSIDE SURFACE OF THE DEVICE, OR BY WIPING THE ENTIRE SURFACE AREA IF IT IS LESS THAN ONE HUNDRED SQUARE CENTIMETERS. THE AMOUNT OF TRITIUM OR PROMETHIUM-147 IN THE WATER USED IN THE HERMETIC SEAL AND WATERPROOF TEST PRESCRIBED BY TEST PARAGRAPH (E) OF THIS RULE SHALL ALSO BE MEASURED. MEASUREMENTS SHALL BE MADE IN AN APPARATUS CALIBRATED TO MEASURE TRITIUM OR PROMETHIUM-147, AS APPROPRIATE. THE DETECTION ON THE FILTER PAPER OF MORE THAN TWO THOUSAND TWO HUNDRED DISINTEGRATIONS PER MINUTE OF TRITIUM OR PROMETHIUM-147 PER ONE HUNDRED SQUARE CENTIMETERS OF SURFACE WIPED OR IN THE WATER OF MORE THAN 0.1 PERCENT OF THE ORIGINAL AMOUNT OF TRITIUM OR PROMETHIUM-147 IN ANY DEVICE SHALL BE CAUSE FOR REJECTION OF THE TESTED DEVICE.

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3701:1-46-46 PROTOTYPE TESTS FOR CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241 OR RADIUM.

AN APPLICANT FOR A LICENSE PURSUANT TO RULE 3701:1-46-37 OF THIS CHAPTER SHALL, FOR ANY TYPE OF SOURCE WHICH IS DESIGNED TO CONTAIN MORE THAN ONE HUNDRED EIGHTY-FIVE BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241 OR RADIUM, CONDUCT PROTOTYPE TESTS, IN THE ORDER LISTED, ON EACH OF FIVE PROTOTYPES OF SUCH SOURCE, WHICH CONTAINS MORE THAN ONE HUNDRED EIGHTY-FIVE BECQUERELS (0.005 MICROCURIES) OF AMERICIUM-241 OR RADIUM, AS FOLLOWS:

PROTOTYPE TESTS	
INITIAL MEASUREMENT	THE QUANTITY OF RADIOACTIVE MATERIAL DEPOSITED ON THE SOURCE SHALL BE MEASURED BY DIRECT COUNTING OF THE SOURCE.
DRY WIPE TEST	THE ENTIRE RADIOACTIVE SURFACE OF THE SOURCE SHALL BE WIPED WITH FILTER PAPER WITH THE APPLICATION OF MODERATE FINGER PRESSURE. REMOVAL OF RADIOACTIVE MATERIAL FROM THE SOURCE SHALL BE DETERMINED BY MEASURING THE RADIOACTIVITY ON THE FILTER PAPER OR BY DIRECT MEASUREMENT OF THE RADIOACTIVITY ON THE SOURCE FOLLOWING THE DRY WIPE.
WET WIPE TEST	THE ENTIRE RADIOACTIVE SURFACE OF THE SOURCE SHALL BE WIPED WITH FILTER PAPER, MOISTENED WITH WATER, WITH THE APPLICATION OF MODERATE FINGER PRESSURE. REMOVAL OF RADIOACTIVE MATERIAL FROM THE SOURCE SHALL BE DETERMINED BY MEASURING THE RADIOACTIVITY ON THE FILTER PAPER AFTER IT HAS DRIED OR BY DIRECT MEASUREMENT OF THE RADIOACTIVITY ON THE SOURCE FOLLOWING THE WET WIPE.
WATER SOAK TEST	THE SOURCE SHALL BE IMMERSSED IN WATER AT ROOM TEMPERATURE FOR A PERIOD OF TWENTY-FOUR CONSECUTIVE HOURS. THE SOURCE SHALL THEN BE REMOVED FROM THE WATER. REMOVAL OF RADIOACTIVE MATERIAL FROM THE SOURCE SHALL BE DETERMINED BY DIRECT MEASUREMENT OF THE RADIOACTIVITY ON THE SOURCE AFTER IT HAS DRIED OR BY MEASURING THE RADIOACTIVITY IN THE RESIDUE OBTAINED BY EVAPORATION OF THE WATER IN WHICH THE SOURCE WAS IMMERSSED.
DRY WIPE TEST	ON COMPLETION OF THE PRECEDING TEST IN PARAGRAPH (D) OF THIS RULE, THE DRY WIPE TEST DESCRIBED IN PARAGRAPH (B) OF THIS SECTION SHALL BE REPEATED.

OBSERVATIONS	REMOVAL OF MORE THAN ONE HUNDRED EIGHTY-FIVE BECQUERELS (0.005 MICROCURIES) OF RADIOACTIVITY IN ANY TEST PRESCRIBED BY THIS SECTION SHALL BE CAUSE FOR REJECTION OF THE SOURCE DESIGN. RESULTS OF PROTOTYPE TESTS SUBMITTED TO THE DIRECTOR SHALL BE GIVEN IN TERMS OF RADIOACTIVITY IN BECQUERELS (OR METRIC MULTIPLE, THEREOF) AND PERCENT OF REMOVAL FROM THE TOTAL AMOUNT OF RADIOACTIVE MATERIAL DEPOSITED ON THE SOURCE.
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3701:1-46-47 PROTOTYPE TESTS FOR ICE DETECTION DEVICES CONTAINING STRONTIUM-90.

AN APPLICANT FOR A LICENSE PURSUANT TO RULE 3701:1-46-40 OF THIS CHAPTER SHALL CONDUCT PROTOTYPE TESTS ON EACH OF FIVE PROTOTYPE ICE DETECTION DEVICES AS FOLLOWS:

PROTOTYPE TESTS	
TEMPERATURE-ALTITUDE TEST	THE DEVICE SHALL BE PLACED IN A TEST CHAMBER AS IT WOULD BE USED IN SERVICE. A TEMPERATURE-ALTITUDE CONDITION SCHEDULE SHALL BE FOLLOWED AS OUTLINED IN <u>STEP ONE THROUGH STEP 10</u> OF TABLE 1 IN RULE 3701:1-46-45 OF THIS CHAPTER.
VIBRATION TESTS	THE DEVICE SHALL BE SUBJECTED TO VIBRATION TESTS AS SET FORTH IN PARAGRAPH (B) OF RULE 3701:1-46-45 OF THIS CHAPTER.
SHOCK TEST	THE DEVICE SHALL BE SUBJECTED TO SHOCK TEST AS SET FORTH IN PARAGRAPH (D) OF RULE 3701:1-46-45 OF THIS CHAPTER.
HERMETIC SEAL AND WATERPROOF TEST	ON COMPLETION OF ALL OTHER TESTS PRESCRIBED BY THIS RULE, THE DEVICE SHALL BE IMMERSSED IN THIRTY INCHES OF WATER FOR TWENTY-FOUR HOURS AND SHALL SHOW NO VISIBLE EVIDENCE OF PHYSICAL CONTACT BETWEEN THE WATER AND THE STRONTIUM-90. ABSOLUTE PRESSURE OF THE AIR ABOVE THE WATER SHALL THEN BE REDUCED TO ONE INCH OF MERCURY. LOWERED PRESSURE SHALL BE MAINTAINED FOR ONE MINUTE OR UNTIL AIR BUBBLES CEASE TO BE GIVEN OFF BY THE WATER, WHICHEVER IS THE LONGER. PRESSURE SHALL THEN BE INCREASED TO NORMAL ATMOSPHERIC PRESSURE. ANY VISIBLE EVIDENCE OF PHYSICAL CONTACT BETWEEN THE WATER AND THE STRONTIUM-90 SHALL BE CONSIDERED LEAKAGE.
OBSERVATIONS	AFTER EACH OF THE TESTS PRESCRIBED BY THIS RULE, EACH DEVICE SHALL BE EXAMINED FOR EVIDENCE OF PHYSICAL DAMAGE AND FOR LOSS OF STRONTIUM-90. ANY EVIDENCE OF LEAKAGE OR DAMAGE TO OR FAILURE OF ANY DEVICE WHICH COULD AFFECT CONTAINMENT OF THE STRONTIUM-90 SHALL BE CAUSE FOR REJECTION OF THE DESIGN IF THE DAMAGE OR FAILURE IS ATTRIBUTABLE TO A DESIGN DEFECT. LOSS OF STRONTIUM-90 FROM EACH TESTED DEVICE SHALL BE MEASURED BY WIPING WITH FILTER PAPER AN AREA OF AT LEAST ONE HUNDRED SQUARE

	<p>CENTIMETERS ON THE OUTSIDE SURFACE OF THE DEVICE, OR BY WIPING THE ENTIRE SURFACE AREA IF IT IS LESS THAN ONE HUNDRED SQUARE CENTIMETERS. THE AMOUNT OF STRONTIUM-90 IN THE WATER USED IN THE HERMETIC SEAL AND WATERPROOF TEST PRESCRIBED IN THIS TABLE SHALL ALSO BE MEASURED. THE DETECTION ON THE FILTER PAPER OF MORE THAN TWO THOUSAND TWO HUNDRED DISINTEGRATIONS PER MINUTE OF STRONTIUM-90 PER ONE HUNDRED SQUARE CENTIMETERS OF SURFACE WIPED OR IN THE WATER OF MORE THAN 0.1 PERCENT OF THE ORIGINAL AMOUNT OF STRONTIUM-90 IN ANY DEVICE, SHALL BE CAUSE FOR REJECTION OF THE TESTED DEVICE.</p>
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3701:1-46-48 ACCEPTANCE SAMPLING PROCEDURES UNDER CERTAIN SPECIFIC LICENSES.

(A) A RANDOM SAMPLE SHALL BE TAKEN FROM EACH INSPECTION LOT OF DEVICES LICENSED UNDER RULES 3701:1-46-16, 3701:1-46-33, OR 3701:1-46-40 OF THIS CHAPTER FOR WHICH TESTING IS REQUIRED PURSUANT TO RULES 3701:1-46-17, 3701:1-46-35, OR 3701:1-46-41 OF THIS CHAPTER IN ACCORDANCE WITH THE APPROPRIATE SAMPLING TABLE IN THIS RULE DETERMINED BY THE DESIGNATED LOT TOLERANCE PERCENT DEFECTIVE. IF THE NUMBER OF DEFECTIVES IN THE SAMPLE DOES NOT EXCEED THE ACCEPTANCE NUMBER IN THE APPROPRIATE SAMPLING TABLE IN THIS RULE, THE LOT SHALL BE ACCEPTED. IF THE NUMBER OF DEFECTIVES IN THE SAMPLE EXCEEDS THE ACCEPTANCE NUMBER IN THE APPROPRIATE SAMPLING TABLE IN THIS RULE, THE ENTIRE INSPECTION LOT SHALL BE REJECTED.

(B) SINGLE SAMPLING TABLES FOR LOT TOLERANCE PERCENT DEFECTIVE:

(1) LOT TOLERANCE PERCENT DEFECTIVE 0.5 PERCENT:

<u>LOT SIZE</u>	<u>SAMPLE SIZE</u>	<u>ACCEPTANCE NUMBER</u>
1 TO 180	ALL	0
181 TO 210	180	0
211 TO 250	210	0
251 TO 300	240	0
301 TO 400	275	0
401 TO 500	00	0
501 TO 600	20	0
601 TO 800	350	0
801 TO 1,000	365	0
1,001 TO 2,000	410	0
2,001 TO 3,000	430	0
3001 TO 4000	440	0
4001 TO 5000	445	0
5001 TO 7000	450	0
7001 TO 10000	455	0
10001 TO 20000	460	0
20001 TO 50000	775	1
50001 TO 100000	780	1

(2) LOT TOLERANCE PERCENT DEFECTIVE ONE PERCENT:

LOT SIZE	SAMPLE SIZE	ACCEPTANCE NUMBER
1 TO 120	ALL	0
121 TO 150	120	0
151 TO 200	140	0
201 TO 300	165	0
301 TO 400	175	0
401 TO 500	180	0
501 TO 600	190	0
601 TO 800	200	0
801 TO 1,000	205	0
1,001 TO 3,000	220	0
3,001 TO 5,000	225	0
5,001 TO 10,000.	230	0
10,001 TO 100,000.	390	1

(3) LOT TOLERANCE PERCENT DEFECTIVE TWO PERCENT:

LOT SIZE	SAMPLE SIZE	ACCEPTANCE NUMBER
1 TO 75	ALL	0
76 TO 100	70	0
101 TO 200	85	0
201 TO 300	95	0
301 TO 400	100	0
401 TO 600	105	0
601 TO 800	110	0
801 TO 4,000	115	0
4,001 TO 10,000	195	1
10,001 TO 100,000	200	1

(4) LOT TOLERANCE PERCENT DEFECTIVE THREE PERCENT:

LOT SIZE	SAMPLE SIZE	ACCEPTANCE NUMBER
1 TO 40	ALL	0
41 TO 55	40	0
56 TO 100	55	0
101 TO 200	65	0
201 TO 500	70	0

501 TO 3,000	75	0
3,001 TO 100,000	130	1

(5) LOT TOLERANCE PERCENT DEFECTIVE FOUR PERCENT:

<u>LOT SIZE</u>	<u>SAMPLE SIZE</u>	<u>ACCEPTANCE NUMBER</u>
1 TO 35	ALL	0
36 TO 50	34	0
51 TO 100	44	0
101 TO 200	50	0
201 TO 2,000	55	0
2,001 TO 100,000	95	1

(6) LOT TOLERANCE PERCENT DEFECTIVE FIVE PERCENT:

<u>LOT SIZE</u>	<u>SAMPLE SIZE</u>	<u>ACCEPTANCE NUMBER</u>
1 TO 30	ALL	0
31 TO 50	30	0
51 TO 100	37	0
101 TO 200	40	0
201 TO 300	43	0
301 TO 400	44	0
401 TO 2,000	45	0
2,001 TO 100,000	75	1

(7) LOT TOLERANCE PERCENT DEFECTIVE SEVEN PERCENT:

<u>LOT SIZE</u>	<u>SAMPLE SIZE</u>	<u>ACCEPTANCE NUMBER</u>
1 TO 25	ALL	0
26 TO 50	24	0
51 TO 100	28	0
101 TO 200	30	0
201 TO 300	31	0

301 TO 800	32	0
801 TO 1,000	33	0
1,001 TO 100,000	55	1

(8) LOT TOLERANCE PERCENT DEFECTIVE TEN PERCENT:

<u>LOT SIZE</u>	<u>SAMPLE SIZE</u>	<u>ACCEPTANCE NUMBER</u>
1 TO 20	<u>ALL</u>	0
21 TO 50	17	0
51 TO 100	20	0
101 TO 200	22	0
201 TO 800	23	0
801 TO 100,000	39	1

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3701:1-46-49 REGISTRATION OF PRODUCT INFORMATION.

- (A) ANY MANUFACTURER OR INITIAL DISTRIBUTOR OF A SEALED SOURCE OR DEVICE CONTAINING A SEALED SOURCE WHOSE PRODUCT IS INTENDED FOR USE UNDER A SPECIFIC LICENSE MAY SUBMIT A REQUEST TO THE DIRECTOR FOR EVALUATION OF RADIATION SAFETY INFORMATION ABOUT ITS PRODUCT AND FOR ITS REGISTRATION.
- (B) THE REQUEST FOR REVIEW MUST BE MADE IN DUPLICATE AND SENT TO THE
OHIO DEPARTMENT OF HEALTH, BUREAU OF RADIATION PROTECTION
35 EAST CHESTNUT STREET, SEVENTH FLOOR
POST OFFICE BOX 118
COLUMBUS, OHIO 43216-0118
- (C) THE REQUEST FOR REVIEW OF A SEALED SOURCE OR A DEVICE MUST INCLUDE SUFFICIENT INFORMATION ABOUT THE DESIGN, MANUFACTURE, PROTOTYPE TESTING, QUALITY CONTROL PROGRAM, LABELING, PROPOSED USES AND LEAK TESTING AND, FOR A DEVICE, THE REQUEST MUST ALSO INCLUDE SUFFICIENT INFORMATION ABOUT INSTALLATION, SERVICE AND MAINTENANCE, OPERATING AND SAFETY INSTRUCTIONS, AND ITS POTENTIAL HAZARDS, TO PROVIDE REASONABLE ASSURANCE THAT THE RADIATION SAFETY PROPERTIES OF THE SOURCE OR DEVICE ARE ADEQUATE TO PROTECT HEALTH AND MINIMIZE DANGER TO LIFE AND PROPERTY.
- (D) THE DIRECTOR NORMALLY EVALUATES A SEALED SOURCE OR A DEVICE USING RADIATION SAFETY CRITERIA IN ACCEPTED INDUSTRY STANDARDS. IF THESE STANDARDS AND CRITERIA DO NOT READILY APPLY TO A PARTICULAR CASE, THE DIRECTOR FORMULATES REASONABLE STANDARDS AND CRITERIA WITH THE HELP OF THE MANUFACTURER OR DISTRIBUTOR. THE DIRECTOR SHALL USE CRITERIA AND STANDARDS SUFFICIENT TO ENSURE THAT THE RADIATION SAFETY PROPERTIES OF THE DEVICE OR SEALED SOURCE ARE ADEQUATE TO PROTECT HEALTH AND MINIMIZE DANGER TO LIFE AND PROPERTY.
- (E) AFTER COMPLETION OF THE EVALUATION, THE DIRECTOR ISSUES A CERTIFICATE OF REGISTRATION TO THE PERSON MAKING THE REQUEST. THE CERTIFICATE OF REGISTRATION ACKNOWLEDGES THE AVAILABILITY OF THE SUBMITTED INFORMATION FOR INCLUSION IN AN APPLICATION FOR A SPECIFIC LICENSE PROPOSING USE OF THE PRODUCT.
- (F) THE PERSON SUBMITTING THE REQUEST FOR EVALUATION AND REGISTRATION OF SAFETY INFORMATION ABOUT THE PRODUCT SHALL MANUFACTURE AND DISTRIBUTE THE PRODUCT IN ACCORDANCE WITH:

- (1) THE STATEMENTS AND REPRESENTATIONS, INCLUDING QUALITY CONTROL PROGRAM, CONTAINED IN THE REQUEST; AND
- (2) THE PROVISIONS OF THE REGISTRATION CERTIFICATE.

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