

Policies and Procedures as Required by N.R.C. license Commitments to NUREG-1556 Vol. 9 Final Report

The following is a collection of Walter L. Robinson & Associate's Suggested Policies and Procedures for:

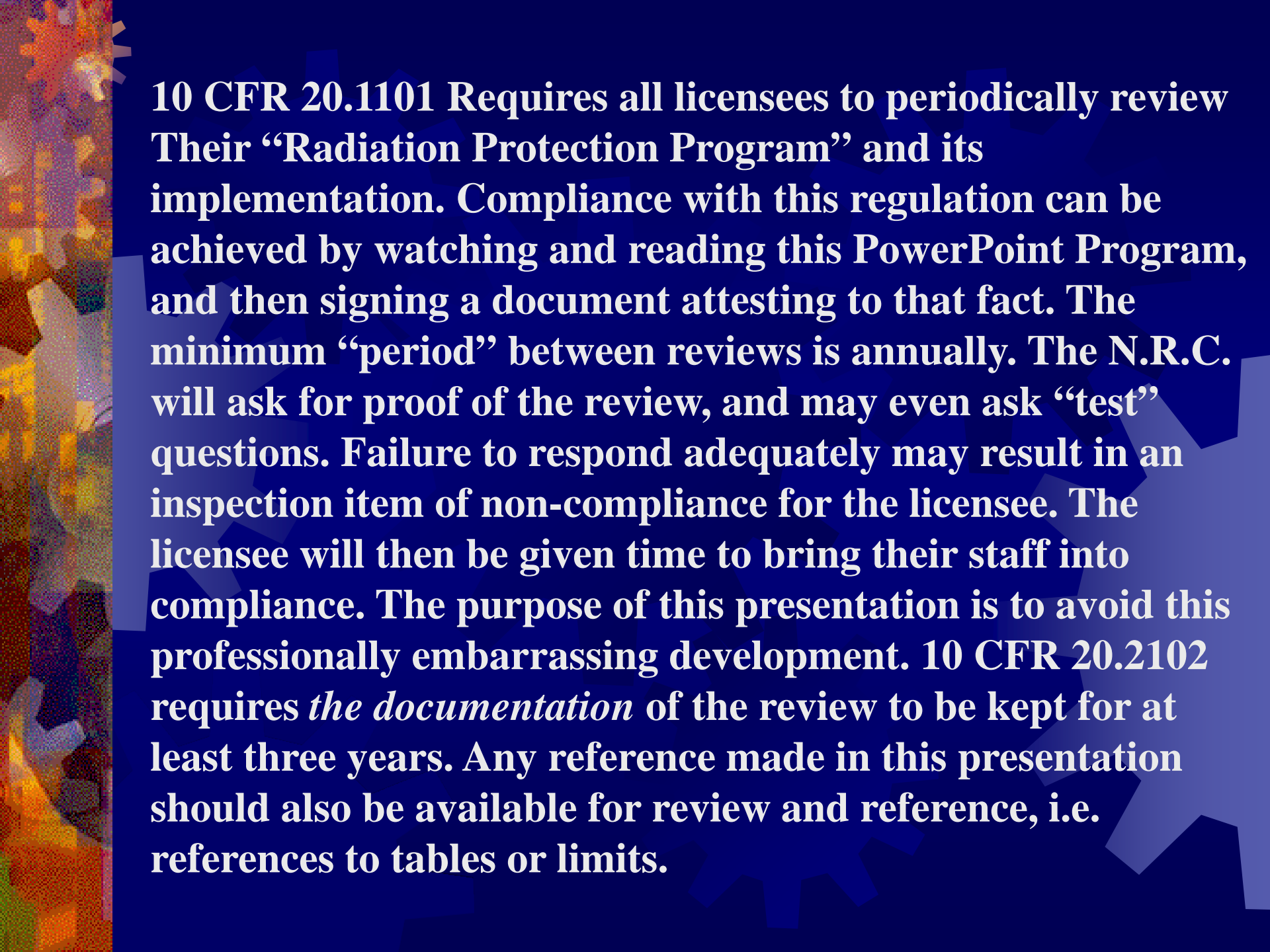
1. Compliance with License Renewal Commitments
2. Compliance with the 10 CFR 20 requirement for an annual review of your Radiation Safety Program

The individual pages can be printed out and inserted directly into YOUR Policy and Procedure

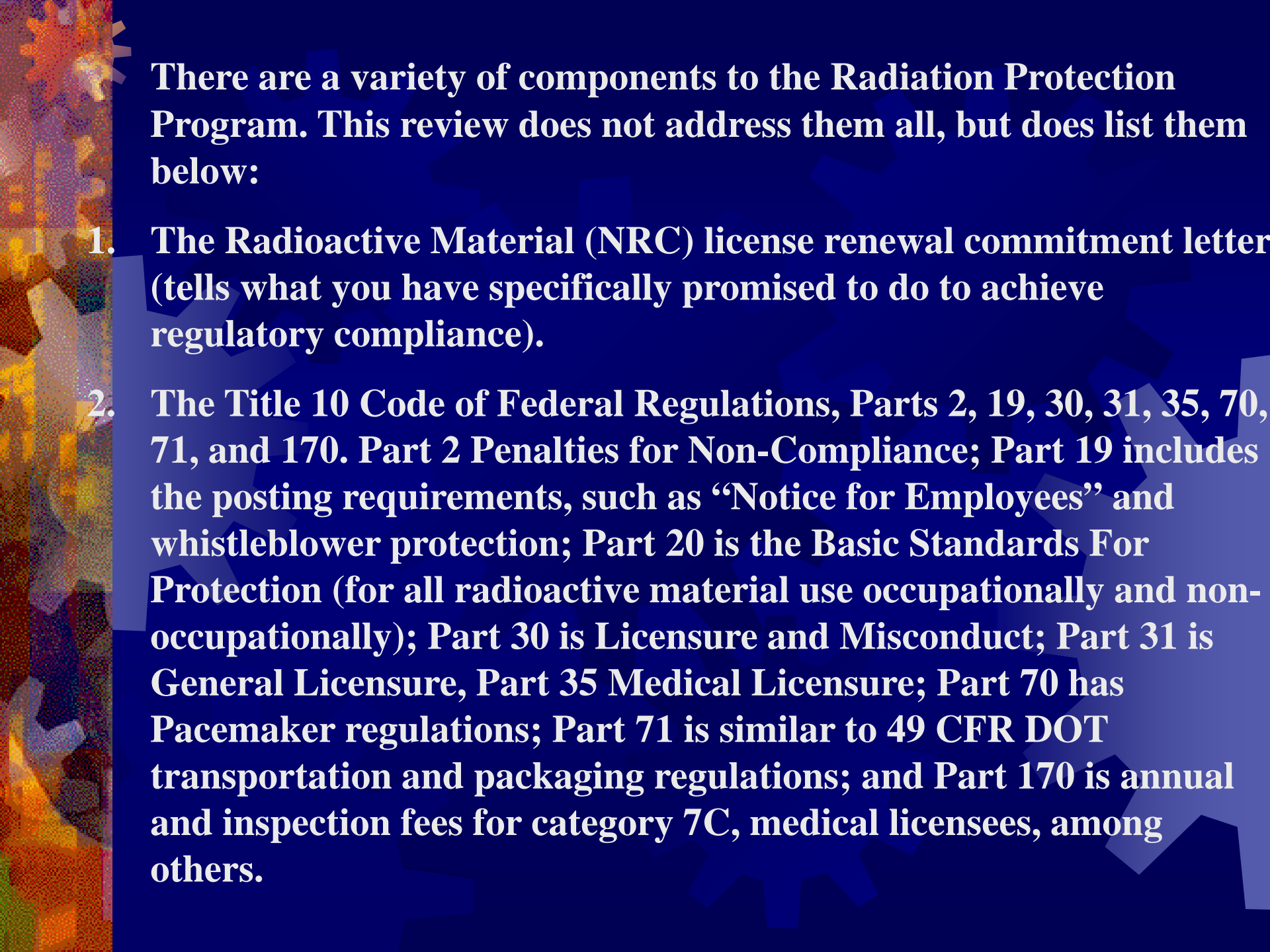
Walter L. Robinson & Associates

Presents:

The required annual radiation safety in-service (10 CFR 19.12 and 10 CFR 35.310) and the required annual review of your Radiation Safety Program (10 CFR 20.1101) This presentation facilitates the N.R.C.-Required (Through License Renewal Commitments) “Development and Implementation of Written Procedures to Maintain Accordance with Applicable 10 CFR Requirements”

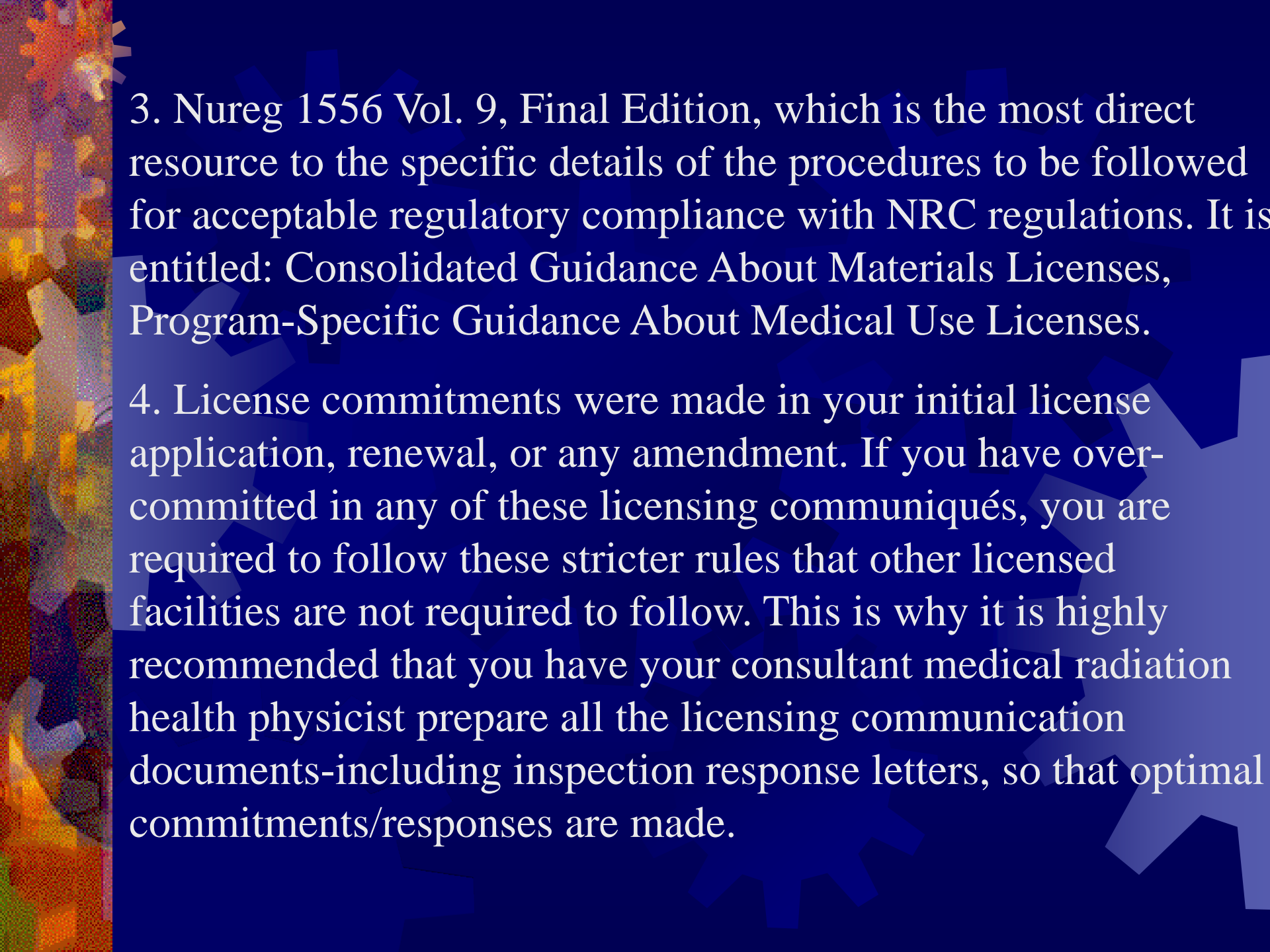
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10 CFR 20.1101 Requires all licensees to periodically review Their “Radiation Protection Program” and its implementation. Compliance with this regulation can be achieved by watching and reading this PowerPoint Program, and then signing a document attesting to that fact. The minimum “period” between reviews is annually. The N.R.C. will ask for proof of the review, and may even ask “test” questions. Failure to respond adequately may result in an inspection item of non-compliance for the licensee. The licensee will then be given time to bring their staff into compliance. The purpose of this presentation is to avoid this professionally embarrassing development. 10 CFR 20.2102 requires *the documentation* of the review to be kept for at least three years. Any reference made in this presentation should also be available for review and reference, i.e. references to tables or limits.



There are a variety of components to the Radiation Protection Program. This review does not address them all, but does list them below:

- 1. The Radioactive Material (NRC) license renewal commitment letter (tells what you have specifically promised to do to achieve regulatory compliance).**
- 2. The Title 10 Code of Federal Regulations, Parts 2, 19, 30, 31, 35, 70, 71, and 170. Part 2 Penalties for Non-Compliance; Part 19 includes the posting requirements, such as “Notice for Employees” and whistleblower protection; Part 20 is the Basic Standards For Protection (for all radioactive material use occupationally and non-occupationally); Part 30 is Licensure and Misconduct; Part 31 is General Licensure, Part 35 Medical Licensure; Part 70 has Pacemaker regulations; Part 71 is similar to 49 CFR DOT transportation and packaging regulations; and Part 170 is annual and inspection fees for category 7C, medical licensees, among others.**

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3. Nureg 1556 Vol. 9, Final Edition, which is the most direct resource to the specific details of the procedures to be followed for acceptable regulatory compliance with NRC regulations. It is entitled: Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses.

4. License commitments were made in your initial license application, renewal, or any amendment. If you have over-committed in any of these licensing communiqués, you are required to follow these stricter rules that other licensed facilities are not required to follow. This is why it is highly recommended that you have your consultant medical radiation health physicist prepare all the licensing communication documents-including inspection response letters, so that optimal commitments/responses are made.

Occupational Dose in Compliance with 10 CFR 20.1101

In addition to the confirmation of following the procedures of Nureg 1556 Vol. 9, Final Edition, Appendix M, we also follow the dose constraint of keeping exposure to the general public to below 10 mREM/yr. due to air emissions as part of our 10 CFR 20.1101 commitment to our A.L.A.R.A. Program to keep radiation exposures constrained to lower than that regulated, if reasonable. To confirm we use the EPA “Comply” report to affirm compliance with this constraint.

To better understand the pertinent details of Appendix M, the reader is directed to read pages M-1 to M-7, where policies and procedures are discussed for: external exposure, internal exposure, summation of doses, investigational levels, declared pregnancy, and dose to the embryo/fetus.

Radiation Survey Meter Calibrations in Compliance with 10 CFR 20 & 35

In addition to the confirmation of following the procedures of Nureg 1556 Vol. 9, Final Edition, Appendix K, we have adequate and appropriate detection (G.M.) and measurement (ion chamber) survey meters present for primary and back-up use. These meters are calibrated annually with their dedicated check sources. Each meter is properly labeled, and meter calibration certificates kept for three years. The meter's operational check sources are checked before each use, or daily. To better understand the commitments to 10 CFR 20.1501 and 10 CFR 35.61, details of Appendix K, the reader is directed to read pages K-1 to K-7, where policies and procedures are discussed for: equipment selection, calibration, efficiency of uptake probes and well counters. In addition we calculate the minimum detectable activity to determine suitable sensitivity of scintillation detectors used for health physics and regulator-required measurements.

Dose Calibrator Quality Control Requirements of 10 CFR 35.60 & 63

We use only unit doses; however, in the event we do not, and to assure accuracy and integrity of our doses we calibrate our dose calibrator in accordance with nationally recognized standards (ANSI Standard N42.13-1986 or manufacturer's instructions (operating manual) in accordance with 10 CFR 35.60, and 10 CR 35.63.

If pure beta-emitter doses are used, our dose calibrator will only be used as a secondary assurance cross-check. We will utilize the manufacturer's assay, and mathematically decay-correct, and volume-correct the prescribed patient dose, being careful to not vary the container thickness composition, size, or shape.

When PET radiopharmaceuticals are assayed, an appropriate lead protective shield will encompass the detector well, which will be manufacturer-calibrated for PET radionuclide use.

Policy and Procedure for Ordering and Receiving Radioactive Material Packages

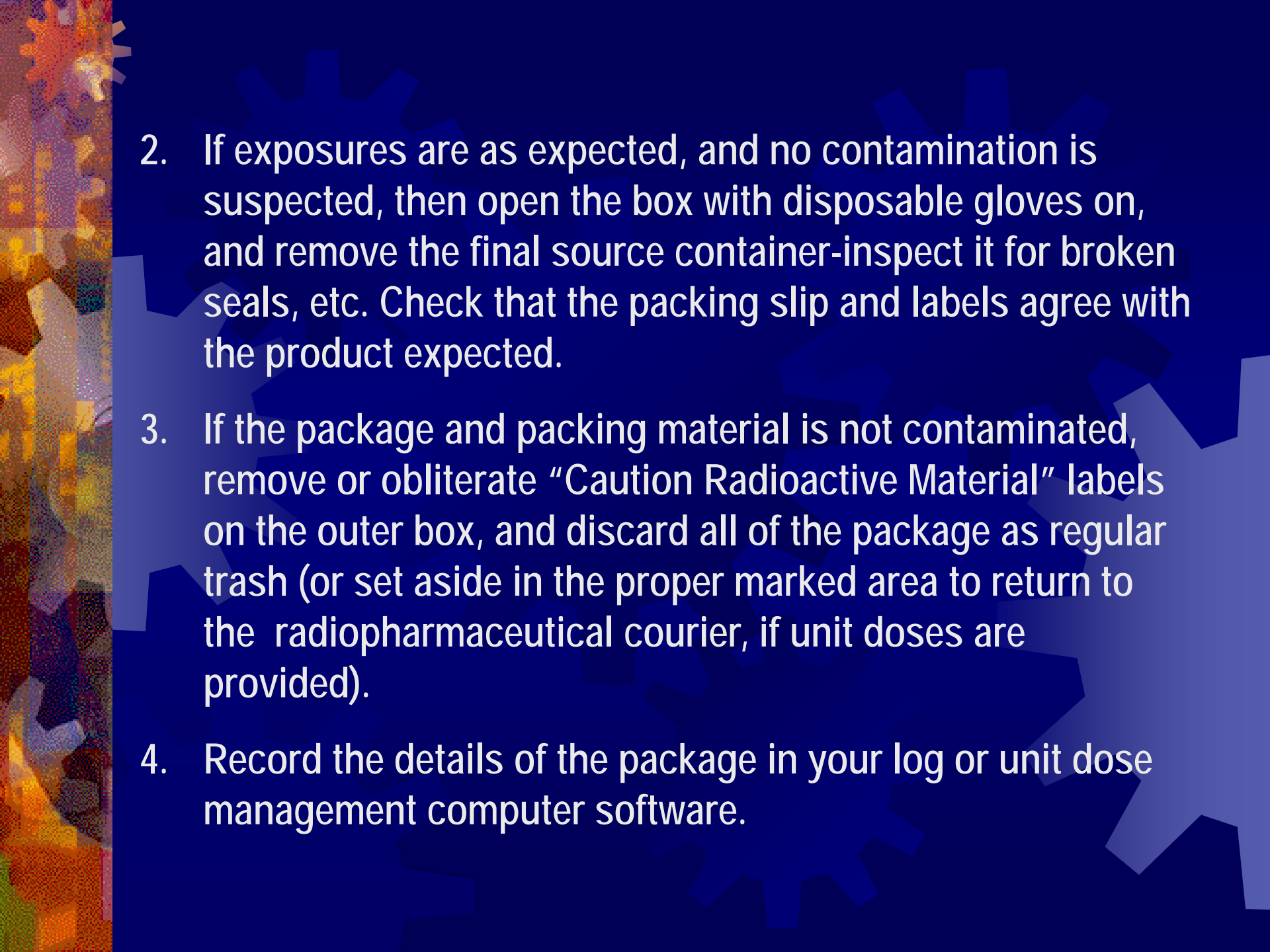
In addition to following Appendix O (Page O-1 to O-2), all radioactive materials will be ordered by the nuclear medicine technologist following the authorized user's prescribed dose, dosage range, or from a pediatric dose calculation. Routine receipt of all radioactive material packages from the radiopharmacies is directly to the nuclear medicine department's hot lab. This is during operating and non-operating hours. Security access will be made for the courier to deliver directly to the hot lab. In the event a DOT-labeled radioactive material package is delivered to a loading dock or alternate off-loading site, staff at these locations are trained* to 1. Refuse delivery-redirecting the courier to the hospital hot lab during non-operating hours, and 2. Call the Nuclear Medicine Technologist on duty for delivery instructions during operating hours.

* Training is by adequately posted document at remote facilities with an annual refresher memo document.

Policy and Procedure for Opening Radioactive Material Packages

In accordance with 10 CFR 20.1906, 10 CFR 71.4, and Nureg 1556 Vol. 9, Appendix P, we ascribe to the following radioactive package opening procedure:


1. Upon receipt of the package in the hot lab from the courier, don disposable gloves, then survey the package with a detection-type (G.M.) radiation survey meter at three feet. The exposure in mR/hr is compared to the transport index (T.I.) on the package label for consistency. If the measured exposure rate is above that expected (from T.I.), then the package is surveyed at about one inch from the surface to assess any focal spot of radioactivity, which might indicate contamination. If contamination is suspected, (i.e. package surface is dented or wet-not due to environmental conditions), the six surfaces are wipe-tested and the wipes are measured on the well scintillation counter in plastic test tubes. If contamination is present (exceeding 22 dpm/cm^2 , or $2200 \text{ dpm/100 cm}^2$), notify the RSO. The courier, the supplier-vendor, and the N.R.C. Regional Office must be notified if the contamination exceeds levels of 10 CFR 71.87(i), or external radiation levels exceeding 10 CFR 71.47 limits. If contaminated, treat as radioactive waste.

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2. If exposures are as expected, and no contamination is suspected, then open the box with disposable gloves on, and remove the final source container-inspect it for broken seals, etc. Check that the packing slip and labels agree with the product expected.
 3. If the package and packing material is not contaminated, remove or obliterate "Caution Radioactive Material" labels on the outer box, and discard all of the package as regular trash (or set aside in the proper marked area to return to the radiopharmaceutical courier, if unit doses are provided).
 4. Record the details of the package in your log or unit dose management computer software.



Policy and Procedure for Safe Handling of Unsealed Radioactive Sources

In accordance with 10 CFR 20.1101, 10 CFR 20.1301, and 10 CFR 35.69, we ascribe to Nureg 1556 Vol. 9, Appendix T unsealed source safe handling procedures. These procedures have been previously known as “Good Housekeeping Rules for Nuclear Medicine Departments”.

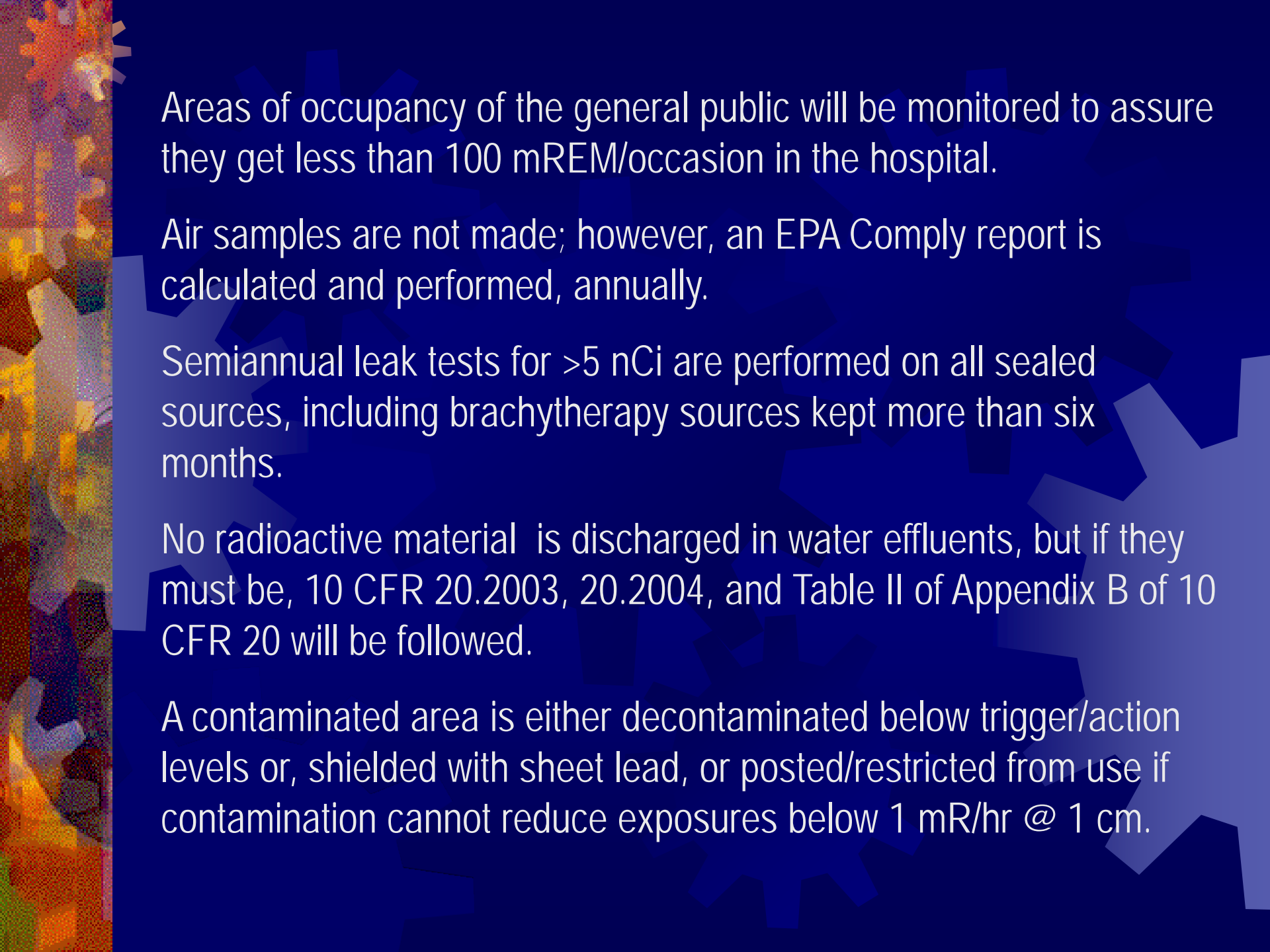


Procedures for Area Surveys are performed in accordance with NRC NUREG 1556 Vol. 9, final version, Appendix R.

Radiation Area Surveys for fixed and removable contamination are performed with a pancake or end-window G.M. detection-type survey meter, with wipes assayed with a well scintillation detector. (Daily, or per use, for injection, preparation, and administration areas. Weekly for storage and waste areas <monthly for <200 uCi use areas>). Patient rooms or patients measured with an ion chamber measurement-type radiation survey meter for room-turnover and patient discharge, respectively. These surveys will be in accordance with 10 CFR 20.1501 and 10 CFR 35.70.

In addition, Xenon air-flow will be checked (surveyed) semiannually (if utilized). Aerosol traps will be checked periodically, but not < annually.

Staff handling >30 mCi I-131 will be bioassayed at the plane of entrance to the thyroid uptake probe, with extension rod removed, within 24 hrs. of the exposure. Assurance is made that <40 nCi is present. MDA is determined annually to assure proper sensitivity to detect 40 nCi. If > 100 nCi found, staff will have medical efforts applied for internal decontamination.



Areas of occupancy of the general public will be monitored to assure they get less than 100 mREM/occasion in the hospital.

Air samples are not made; however, an EPA Comply report is calculated and performed, annually.

Semiannual leak tests for >5 nCi are performed on all sealed sources, including brachytherapy sources kept more than six months.

No radioactive material is discharged in water effluents, but if they must be, 10 CFR 20.2003, 20.2004, and Table II of Appendix B of 10 CFR 20 will be followed.

A contaminated area is either decontaminated below trigger/action levels or, shielded with sheet lead, or posted/restricted from use if contamination cannot reduce exposures below 1 mR/hr @ 1 cm.

ACTION LEVELS FOR CONTAMINATION AND AREA SURVEYS

Action Levels for Removable Surface Contamination:

Restricted Areas: 20,000 dpm/100 cm²; 2,000 dpm for I-131

Unrestricted Areas: 1000 dpm/100 cm²; 200 dpm for I-131

Action Levels for the results of Area Surveys:

Restricted Areas: <5 mR/hr

Unrestricted Areas: <0.1 mR/hr

Procedures to Control Decontamination Spills

To meet the requirements of 10 CFR 20.1101, we follow the procedure set forth in NRC NUREG 1556, Vol. 9, final version, Appendix N pertaining to minor and major spills.

We also ascribe to Appendix N for Procedures pertaining to handling "Emergency Surgery of Patients Who Have Received Therapeutic Quantities of Radionuclides" and "Autopsy of Patients Who Have Received Therapeutic Quantities of Radionuclides".

Procedures to Manage Radioactive Waste

In accordance with the regulations 10 CFR 20 Subpart K, 10 CFR 20.1101, and 10 CFR 35.92 we ascribe to the Procedures in NRC NUREG Vol. 9, final version, Appendix W for:

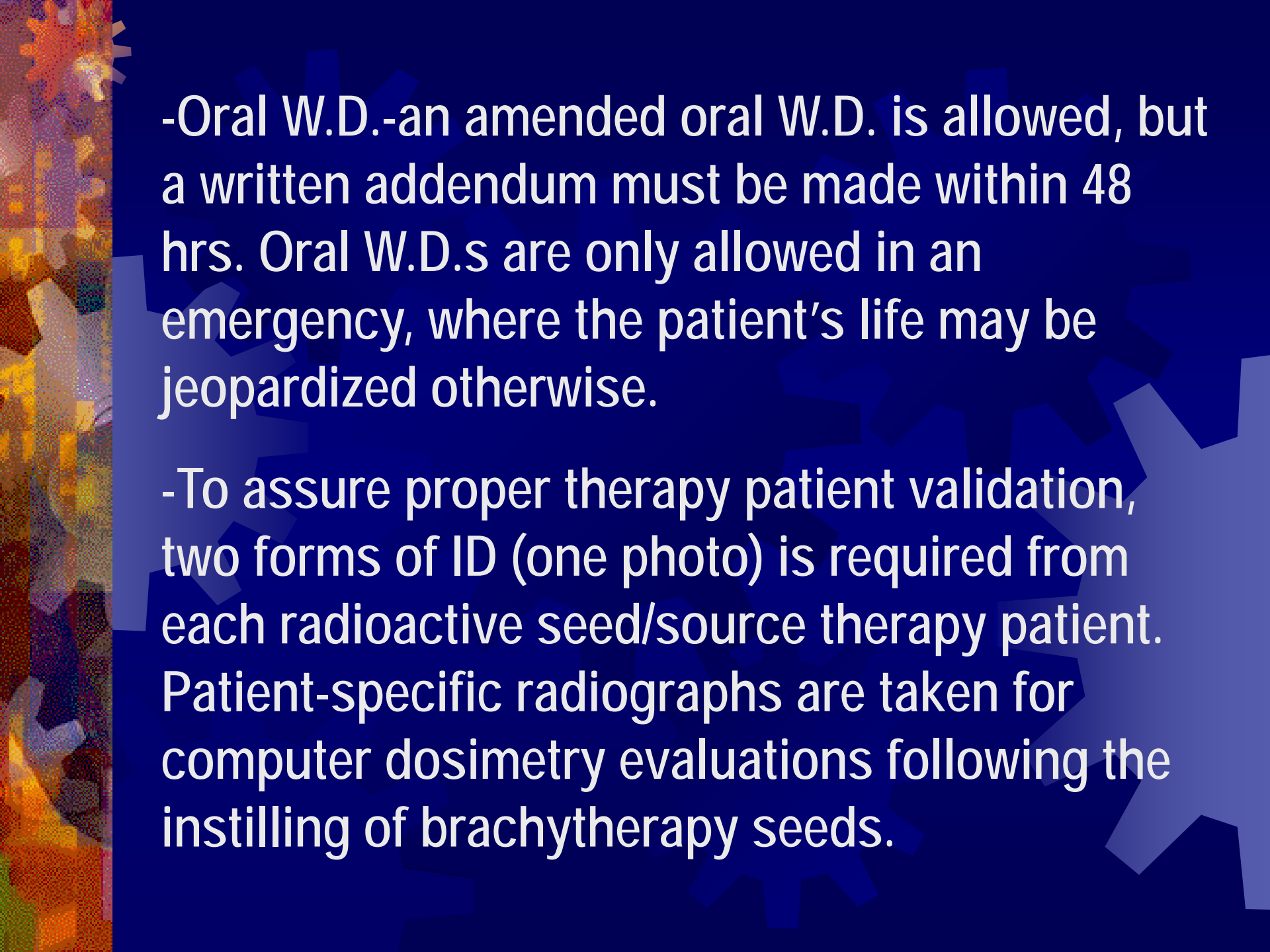
1. Decay-in-storage
2. Return of License Material to Authorized Recipients
3. Staff will Annually Review Hazmat Procedures for Return of Radioactive Materials and keep all shipping receipts
4. All unused brachytherapy seeds will be returned to the manufacturer of origin within 6 months. If not a leak test will be performed on these sealed sources.
5. All unused shipping boxes will have all labels defaced or obliterated as to not indicate "radioactive material" before disposal in regular trash.
6. Any nuclear pacemakers will be returned to the hospital that implanted them, for their return to the original manufacturer.

Written Directives

-Written directives are authorized user physician's prescriptions including details of >30 uCi I-125 or I-131 unsealed source diagnostic procedures and I-131 therapeutic procedures. In addition, brachytherapy sources utilizing I-125 and Pd-103 require written directives also. Also Ir-192 HDR, if present.

-These directives follow the regulations and suggestions of 10 CFR 35.27, 40, 41, 2040, and 2041, and Appendix "S" of NRC Nureg 1556 Vol. 9, final edition.

-Standard W.D. –contains patient's name, radiopharmaceutical, radionuclide, prescribed dose, route of administration for unsealed source therapies. For brachytherapies it must contain the patient's name, the treatment site, radionuclide, dose prescribed, # sources (ordered and final # seeds used), total source strengths, time of treatment, and total prescribed dose. It must be made before administration of dose to the patient.

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-Oral W.D.-an amended oral W.D. is allowed, but a written addendum must be made within 48 hrs. Oral W.D.s are only allowed in an emergency, where the patient's life may be jeopardized otherwise.

-To assure proper therapy patient validation, two forms of ID (one photo) is required from each radioactive seed/source therapy patient. Patient-specific radiographs are taken for computer dosimetry evaluations following the instilling of brachytherapy seeds.

Policy on the Release of Radioactive Patients with Therapy Doses

We comply with 10 CFR 35.75 and 35.2075 and Appendix U of Nureg 1556 Vol. 9, final edition.

Our policy is designed to keep any member of the general public, family, or caregivers exposure to less than 500 mREM (5 mSv) This assumes that each member of the general public has only this exposure. Ideally, each exposure should be designed to keep the exposure as close to 100 mREM as possible, in case the individuals involved receive other exposures through the year. Therefore, instructions are given to patients to achieve an ALARA constraint reduction from the calculated allowed release of 500 mREM to 100 mREM.

In the case of diagnostic or therapeutic radiopharmaceutical exposure to a breast-feeding child which could exceed 100 mREM, we recommend cessation of breast-feeding with written instructions.

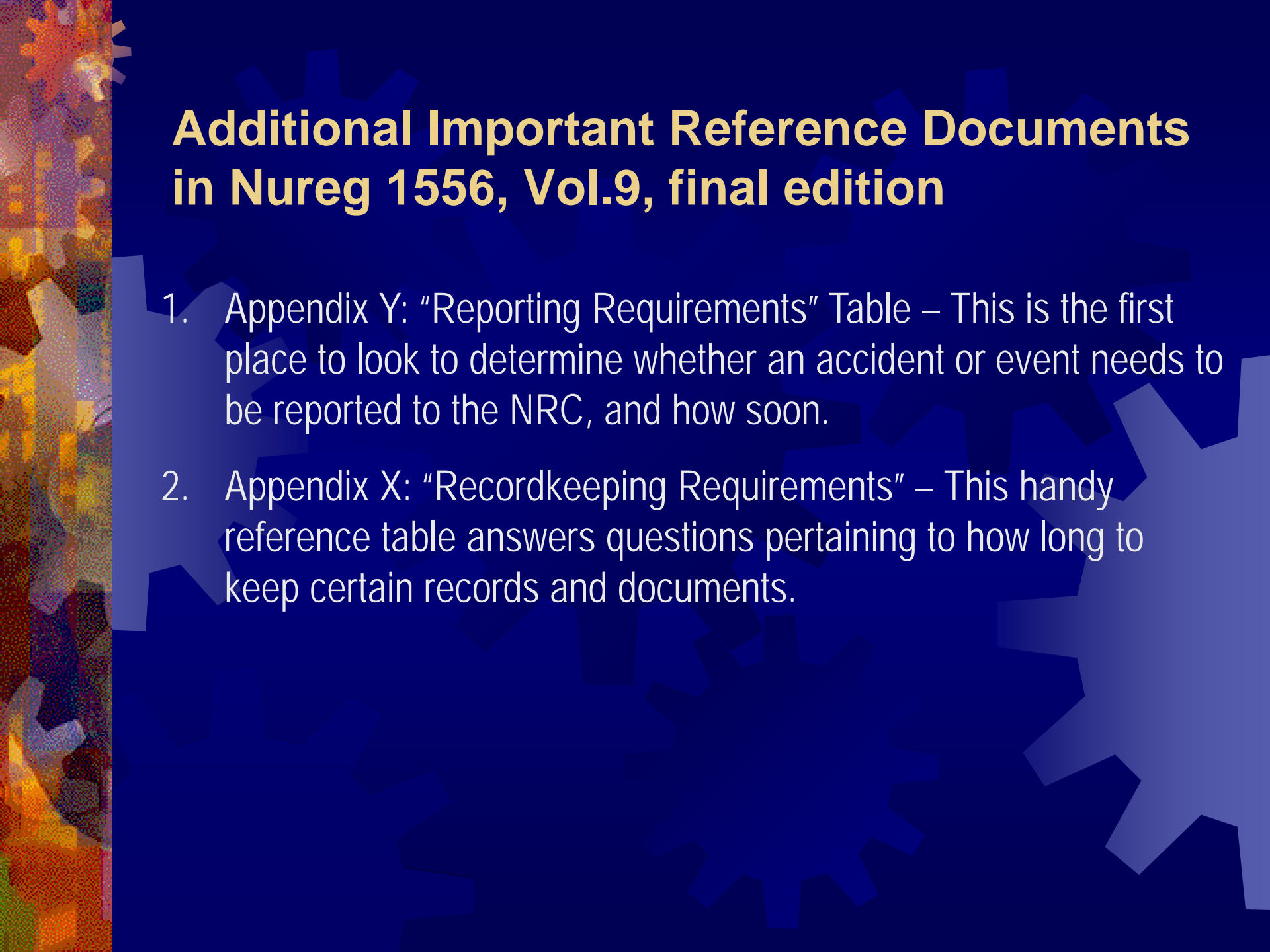
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Authorized Users (NRC-Licensed Physicians) determine the suitability of patients for outpatient release or necessity to remain as an inpatient.

For inpatients not released (for example, I-131 thyroid ablations), the patient remains in a private room prepared with absorbent paper, disposable gloves, food trays, plastic bags. Barriers must be erected to supplement walls with adjacent patients areas of occupancy (one foot from wall) exceeding 2 mR/hr. When patient exposure, measured 1 foot from the bladder, is less than 7 mR/hr, they can be discharged, with written patient precautions. The room is then surveyed to assure all contamination is gone, before turning it over to the next patient. If contamination is found, it is decontaminated to below 200 dpm/cm². Nursing care follows specific written instructions. Radioactive therapy patient attending nurses must use pocket ionization dosimeters if they enter the room. They must receive radiation safety in-services either annually or for every patient.

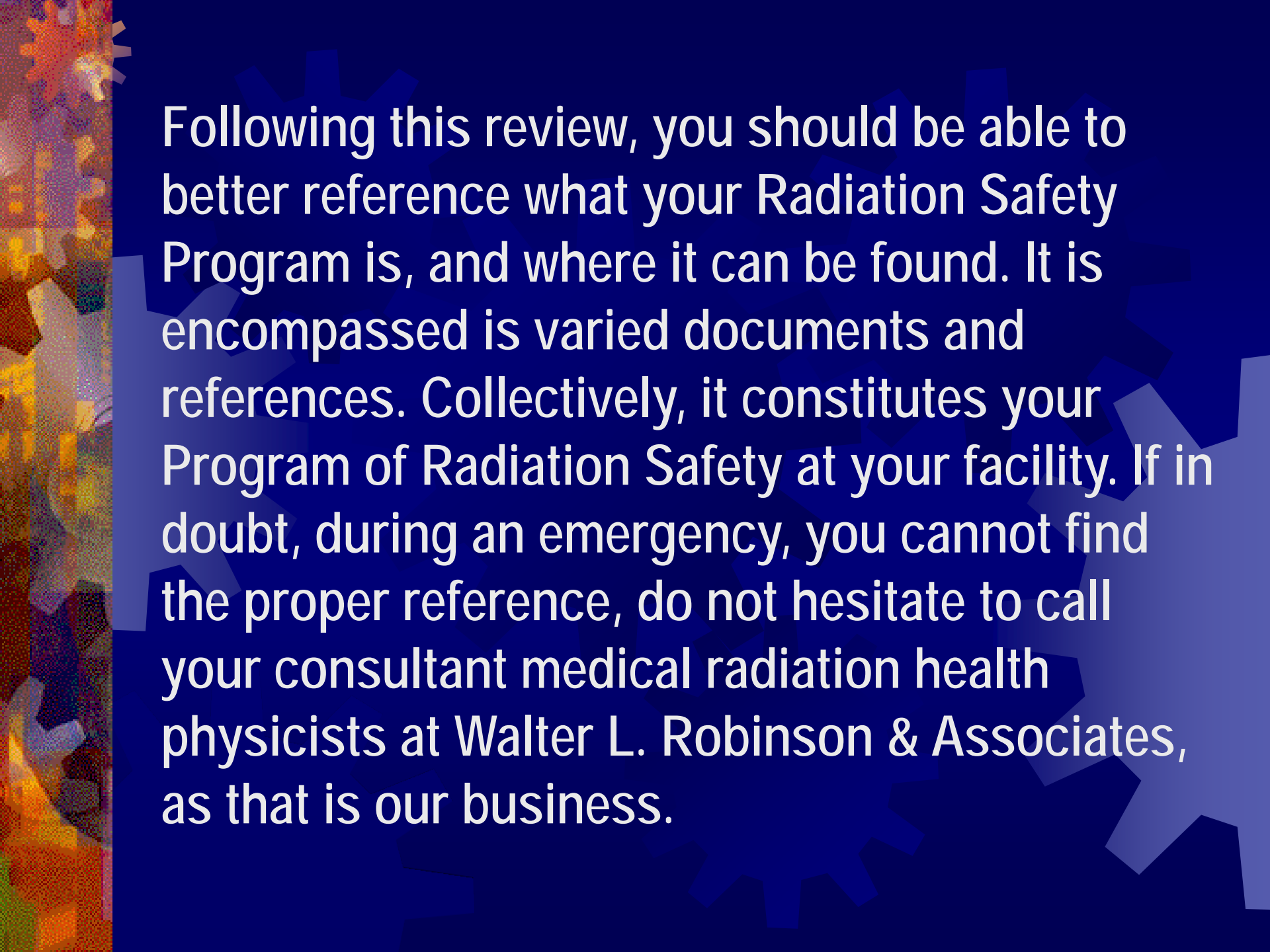
DOT Radioactive Material Packaging and Shipping Regulations, etc.

1. We provide Hazmat training to all staff receiving or returning radioactive materials.
2. We have a copy of DOT regulations 49CFR172 and 49CFR173 for reference (www.dot.gov).
3. 10CFR 71 is the NRC's regulations that pertain to radioactive packages and shipping.
4. 10 CFR 70 is the NRC's regulations that pertain to nuclear-powered pacemakers, and their disposal and reclamation responsibility.
5. 10 CFR 2 describes the enforcement actions that can be taken by the NRC for serious and other violations.
6. We provide instructions to morticians who contemplate cremation of radioactive therapy patients following NRCP references and guidance.
7. Appendix Z of Nureg 1556 Vol. 9, final edition is a handy resource for references to DOT regulations of interest, once you acquire a copy of the Title 49 CFR 172 and 173 regulations.



Additional Important Reference Documents in Nureg 1556, Vol.9, final edition

1. Appendix Y: "Reporting Requirements" Table – This is the first place to look to determine whether an accident or event needs to be reported to the NRC, and how soon.
2. Appendix X: "Recordkeeping Requirements" – This handy reference table answers questions pertaining to how long to keep certain records and documents.

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Following this review, you should be able to better reference what your Radiation Safety Program is, and where it can be found. It is encompassed in varied documents and references. Collectively, it constitutes your Program of Radiation Safety at your facility. If in doubt, during an emergency, you cannot find the proper reference, do not hesitate to call your consultant medical radiation health physicists at Walter L. Robinson & Associates, as that is our business.