FINAL APPLICATION
VOLUME 2
AMENDED AGREEMENT FOR URANIUM RECOVERY REGULATION

STATE OF UTAH

DIVISION OF RADIATION CONTROL
UTAH DEPARTMENT OF ENVIRONMENTAL QUALITY

JANUARY 2003

VOLUME 2

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DIVISION OF RADIATION CONTROL

TECHNICAL PROCEDURES FOR LICENSE REVIEW

Radioactive materials licensing is a process whereby applicants are approved to receive, possess, and use radioactive materials. Technical personnel should understand the concepts of R313-12, -19, -21, -22, -25, -32, -34, -36, and -38. These regulations codify standards for radiation protection and describe the limitations for using different types of radioactive material in various circumstances.

As license reviewers, we review and approve the use of the material, qualifications of the person, and the place of use, as requested. There are several basic questions which should be asked (and answered) to preface this license review procedure. These are:

I. What is a license review?

II. How do you do a license review?

III. When do you do a license review?

IV. Who does the license review?

V. Why do a license review?

This procedure answers each one of these questions - and leaves room for changes. Adequate radioactive materials programs must have personnel and procedures that address each of these questions.

I. What is a license review?

A license review is an evaluation, based on health physics principles, of a request to:

- o change or update an existing license, or
- o to request authorization for a new use condition in an existing license, or
- o to request a new license and authorization, or
- o to request a new or unusual use of radioactive material.

The license review is designed to assure that the uses of, and authorizations for, radioactive material will not present a hazard to the general public or to the workers. It is the DRC's job, therefore, to assure that license reviewers are well trained in health physics principles and understand the rules governing the safe handling of radioactive material.

II. How do you do a license review?

The license review is based on common sense and health physics principles. Using the appropriate review check sheet and licensing guidance available, the reviewer must read the requestor's material, and decide if it meets DRC safety criteria. The check sheets help assure safety criteria are addressed.

After safety criteria has been reviewed, the reviewer writes a Request for Information Letter or if there are no deficiencies, the reviewer writes a draft license. After peer and supervisory review, the license is issued.

III. When do you do a license review?

A license review is done any time a licensee submits a request for a license amendment (change to an existing license) or an applicant requests a new license or a renewal of an existing license. The DRC is obligated to review these applications in a timely manner.

IV. Who does the license review?

The license review is done by at least two persons: a Technical Reviewer (Primary Reviewer) and a Peer Reviewer. The Technical Reviewer completes the first (Phase I) review of a licensing action. This person has the responsibility to identify any gross health and safety deficiencies in a license application or amendment request, prepare Request for Information letters, and write a draft version of the licensing action.

The Technical Reviewer should use appropriate standard guidance to review actions to assure proper quality control, to conform to regulatory positions and evaluate health and safety issues. Various documents may be useful for license reviews and processing: NCRP guidelines, ANSI standards, NUREG publications, NRC Standard Review Plans (SRPs), CRCPD guidelines and many other publications. Advisory Committees and Legal Assistance from the DRC's legal support also should be available. DRC procedures should identify available guidance and provide a framework on which programs may obtain technical or legal assistance. *License reviewers should remember that good health physics practices guide the reviewers' evaluations of any action.*

The Peer Reviewer performs a second (Phase II) review of the licensing action. The purpose of this review is to serve as a quality control check on the accuracy of decisions made in Phase I, to issue any Request for Information letter, and to prepare a final copy of the licensing action for approval and signature.

V. Why do a license review?

License reviews are done to:

- o Issue licenses
- o Issue amendments to licenses
- o Assure health and safety criteria are applied to radioactive materials licenses.

PROCEDURE FOR HANDLING LICENSE ACTIONS
(See the Flow Chart provided as Exhibit A.)

Flow Chart Summary

1. The applicant's submission is logged into the DRC mail log tracking system by an Office Technician III. After the submission has been logged into this system, the action item is given to the Support Services Coordinator.

2. The Support Services Coordinator (SSC) logs the action into the DataEase database and the Excel tracking spreadsheet. The SSC also prepares the Licensing Action Routing Sheet.

3. The SSC must determine if the applicant's submission is a renewal of an existing radioactive materials license.

   3.A If the submission is not a renewal, the SSC prepares a letter to the applicant. The letter acknowledges DRC's receipt of the action. Next, the SSC gives the item to a Technical Reviewer for a Phase I Review.

   3.B If the submission is a renewal application, the SSC must determine if it was filed in a timely manner. All licensees who send applications to the DRC so that they are received at least 30 days before the expiration date are sent a letter acknowledging DRC's receipt of the license renewal. This letter states that the submission was filed in a timely manner. Any licensee who does not send the license renewal in a timely manner receives a letter acknowledging DRC's receipt of the renewal. Next, the SSC gives the action item to a license reviewer for a Phase I Review. Note that some renewal submissions may require enforcement action.

4. A Phase I License Review is performed in accordance with the following:

Name(s)	Assignment(s)
Don	PHASE I 1. Enter Sign-Out Date on Routing Sheet and complete Licensing Action Routing Sheet for Phase I review. 2. Enter date in "Phase I Start Date" and "By" in EXCEL license action tracking spread sheet. 3. Perform a thorough and complete initial review of licensing action. 4. For New or Renewal actions, complete appropriate license review check list. 5. If information or commitments are lacking, draft Request for Information letter. 6. Place draft license, cover letter and Request for Information letter (if needed) in RAD/COMMON/OLD_LIC. Record file names on Routing Sheet. 7. Enter Phase I Completion Date in EXCEL license action tracking spread sheet. 8. Review Licensing Action Routing Sheet entries.

5. A Phase II License Review is performed in accordance with the following:

Name(s)	Assignment(s)
Gwyn, Julie and/or Phil	PHASE II 1. Determine if necessary, who will perform Phase II review. 2. Enter Phase II Start Date and By in EXCEL license action tracking spread sheet. 3. Perform secondary review of licensing action. 4. Telephone licensee if necessary to confirm or clarify information. 5. If additional information or commitments are missing, add to Request for Information letter. 6. If needed, final Request for Information letter. (Licensee contact for letter now becomes Gwyn, Julie and/or Phil). 7. Final licensing action and cover letter. 8. Enter Phase II Completion Date in EXCEL license action tracking spread sheet. 9. Review and complete License Action Routing Sheet. 10. The responsibility for completion of licensing action rests with Gwyn, Julie and/or Phil.

6. After completion of the license review, the action is routed to the Section Manager. All actions are closed out on the Excel spread sheet. The manager also performs a supervisory review on each tenth licensing action as well as all actions processed for major licensees. The Licensing Action Routing Sheet is used to document the supervisory review.

7. The action is presented to the Executive Secretary for review and signature as an official license amendment.

8. An Office Technician III logs the action in the outgoing mail log, photocopies the action, and distributes a file copy to the licensing staff.

9. Final data entry notations are made into the DataEase database and the file copies are placed in the licensee's file folder.

NEW LICENSE APPLICATIONS

1. Using an appropriate review checklist, confirm that operating and emergency procedures are adequate and that all items on the application are complete. In particular:

   - o Application signed and dated by management.
   - o RSO and authorized users designated; training adequate.
   - o Place of use authorized; surveys and environmental factors addressed if appropriate.
   - o Leak test, waste disposal, survey, RAM ordering and package opening procedures adequate.
   - o Instrumentation and calibration adequate.
   - o RAM, quantity, form, use designated with adequate procedures.
   - o Other conditions: bioassay, maintenance, distribution, etc.

2. Confirm that all fiscal documents have been received and are being processed. The DRC cannot issue a new license without payment.

3. Identify on the checklist if a prelicensing inspection should be performed. If appropriate, this should be scheduled with an inspector.

4. Follow the steps for Phase I and Phase II review.

5. New licenses should be issued in a timely manner.

6. All involved in review and processing of an application should sign off on the tracking sheet.

RENEWAL APPLICATIONS

1. Renewal applications should be complete, stand-alone applications. Using an appropriate review checklist, confirm that operating and emergency procedures are adequate and that all items on the application are complete. In particular:

   - o Application signed and dated by management.
   - o RSO and authorized users designated; training adequate.
   - o Place of use authorized; surveys and environmental factors addressed if appropriate.
   - o Leak test, waste disposal, survey, RAM ordering and package opening procedures adequate.
   - o Instrumentation and calibration adequate.
   - o RAM, quantity, form, use designated with adequate procedures.
   - o Other conditions: bioassay, maintenance, distribution, etc.

2. Identify on the checklist if a prelicensing inspection should be performed. If appropriate, this should be scheduled with an inspector.

3. Follow the steps for Phase I and Phase II review.

4. Renewal licenses should be issued in a timely manner.

5. All involved in review and processing of an application should sign off on the tracking sheet.

AMENDMENT REQUESTS

1. Review amendment request carefully. Confirm that:

   - o For authorized user changes, training documents are complete and adequate.
   - o For medical facilities, confirm that the RSC has authorized the user applicant and that a Preceptor Statement or board certification is submitted with the request.

- o For industrial gauge facilities, confirm that training certificates are included with individual requests.

- o If place of authorized use has changed, that surveys and environmental factors are addressed if appropriate; state should verify when appropriate.

- o Leak test, waste disposal, survey, RAM ordering and package opening procedures have changed, that documentation is adequate.

- o If instrumentation and calibration request is made, that procedures are adequate.

- o If RAM, quantity, form, or use change is requested, that there are adequate procedures submitted.

- o If other activities such as gauge maintenance, distribution, etc. are requested, confirm that safe operating procedures and techniques are submitted.

2. If the amendment is a major change in the License Type, confirm that all fiscal aspects of the change have been cleared through the Support Services Coordinator.

3. Identify if a prelicensing inspection should be performed. If appropriate, this should be scheduled with an inspector.

4. Follow the steps for Phase I and Phase II review.

5. Amendments should be issued in a timely manner.

6. All involved in review and processing of an application should sign off on the tracking sheet.

PROCEDURE FOR TERMINATION OF LICENSES

1. Documents needed

   - o Written request for termination

   - o Supporting details

     Copies of transfers, preferably of receipts by recipient with details

     If sealed source and not disposed of as waste; need LT records

     If unsealed, long-lived material needs:

     copies of licensee close out surveys

by whom? date? qualifications of person?

instrument? calibration date?

maps, diagrams of surveys

Statement of decontamination criteria authorized by DRC

Current license as far back as possible

Check for amendments deleting previously authorized materials - what was their disposition?

Cross check with termination request - everything accounted for?

Check for unusual conditions, amendments

- Inspection reports as far back as possible

  Check and cross check with license and with termination request regarding relocations and RAM used

  Check for indication/citation of unauthorized RAM, and use or disposal

  Burials?

  Check for indications of incidents, spills, losses of RAM? Bad compliance history?

  Get correspondence as far back as possible

  Reports of incidents, losses

- DRC close-out surveys/inspections

  A must for most users of unsealed, long lived RAM (e.g. H-3, C-14, I-125, etc.) users and for some ss users, e.g., w/ poor compliance history

  Inspections should include:

  surveys of some points evaluated by licensee

  surveys where contamination could be expected (restricted areas)

surveys for contamination where none should have occurred (unrestricted areas, e.g. soils, drains, sewers, lobbies, offices and homes)

records stating decontamination criteria authorized by state:

instrumentation used and calibration

who did surveys

review of disposition of radioactive waste generated by licensee

decontamination activities: solid, liquid

review of decontamination activities - personnel exposures and monitoring including bioassay or airborne activity

strong documentation of results

review of records of disposition/transfer of RAM and inventories

2. Other Involved Parties

- o In addition to those above:

In cases of transfer of RAM, verify recipients were both authorized for RAM and received it

Discussions (not just exchanges of questions) between license reviewer and inspector are essential - talk about incidents, telephone conversations, and other occurrences that are remembered

Make sure everything is covered

Look for employees with institutional memories

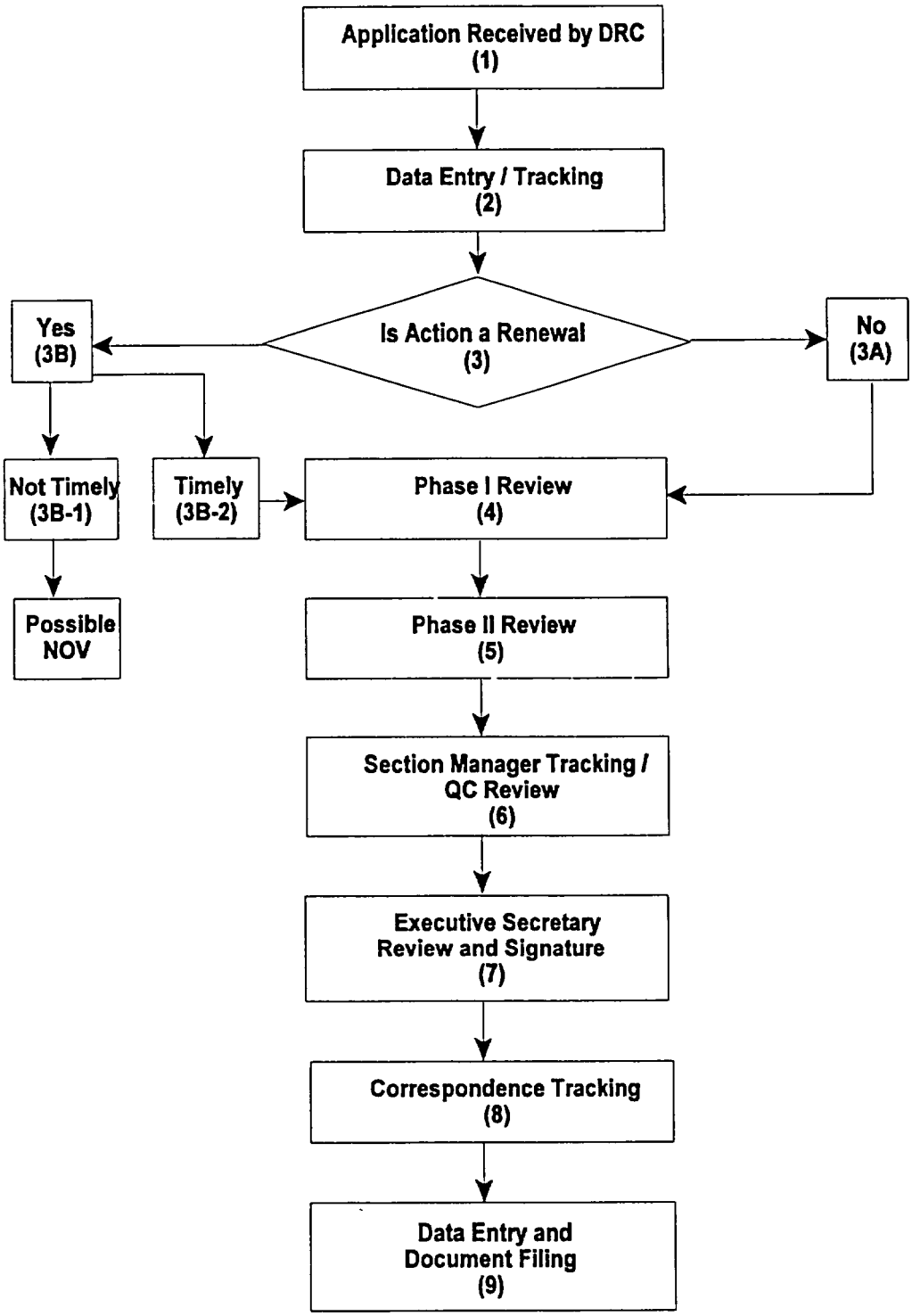
3. Miscellaneous

- o Watch out for General Licensed material used by specific licensees, e.g. instrument calibration sources.
- o On transfer of RAM to out-of-state licensees, don't hesitate to call NRC or State Radiation Control Program to verify recipient is properly licensed and to request verification that RAM was received.

- Be thorough and skeptical - it's your last chance to deal with the applicant as a licensee.

- Finally - are out cards removed from main file drawers and are files placed in proper storage boxes?

Exhibit A


Application Received by DRC (1)
Data Entry / Tracking (2)
Is Action a Renewal (3)
Yes (3B)
No (3A)
Not Timely (3B-1)
Timely (3B-2)
Phase I Review (4)
Possible NOV
Phase II Review (5)
Section Manager Tracking / QC Review (6)
Executive Secretary Review and Signature (7)
Correspondence Tracking (8)
Data Entry and Document Filing (9)

UTAH DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

EXPIRED LICENSE POLICY & PROCEDURE

The following steps are taken regarding expiring licenses:

I. Approximately 2 months in advance a list of expiring licenses are developed using the dataease program. Standard letter glossary 314-number 1 (copy attached), is sent along with the appropriate regulatory guide and license application form.

II. NRC Procedure 83895 Section 02.03(a) and (b) and Bureau guidance information numbers 1 through 3 are followed when licenses expire.

III. Licensees who do not timely file a renewal application are sent a Notice of Violation using standard glossary 314-number 9 (copy attached), with the appropriate additional statements inserted as necessary. NRC Procedure 83895 Section 02.03(c) and Bureau guidance information number 4 and 5 are followed.

IV. The issuance of a new license number when the original license has expired will be reviewed on a case-by-case basis.

UTAH DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

EXPIRED LICENSE GUIDANCE INFORMATION

The following will be effective in the event a license expires.

1. The licensee never acquired licensed material.

   Request a written statement that material was never acquired and that final termination of the license is requested.

2. The licensee already disposed of the licensed material.

   Request written documentation as to the appropriate disposition of the licensed material, a statement as to the retention of all required records, and a formal request to terminate the license.

3. The licensee currently possesses licensed material and does not plan to renew the license.

   a. Issue a Notice of Violation for possession of radioactive material without a valid radioactive material license. Inform the licensee to dispose of the material to an authorized recipient.

   b. Request written documentation as to the appropriate disposition of the licensed material, a statement as to the retention of all required records, and a formal request to terminate the license.

4. The licensee currently possesses licensed material and plans to renew the license.

   Issue a Notice of Violation for possession of radioactive material without a valid license. Instruct the licensee to store the material and submit an application to renew the license. If adequate storage facilities are not available instruct the licensee to transfer the material to an authorized recipient until the renewed license is issued.

5. The licensee currently possesses licensed material and has submitted an application to renew the license.

   Issue a Notice of Violation for possession of radioactive material without a valid license. Instruct the licensee to store the material. If adequate storage facilities are not available instruct the licensee to transfer the material to an authorized recipient until the renewed license is issued.

The issuance of a new license number when the original license has expired will be reviewed on a case-by-case basis.

Craig W Jones
Approved

Jan 10, 1990
Date

GLOSSARY 314 CALL NUMBER 1

DATE

ADDRESS

Re: Radioactive Material License No. _____

Dear _____:

Your Utah Radioactive Materials License No. UT _____ will expire on _____. You will need to carefully follow the enclosed guide in addressing all items of the application form to complete your license renewal. You may make reference to previous submissions to the Utah Burerau of Radiation Control by following the guide procedure titled "Renewal of a License".

If you do not wish to renew your license, please submit a letter which describes the disposition of your radioactive material and the provisions that have been made for the retention of all records required by Utah Radiation Control Rules and your current license.

Please note: R447-22-37(2) provides that if your application for renewal is received in our office 30 days prior to the expiration of your present license, extension of the expiration date is automatic. Your renewal application fee (R447-70-7) of $_____, must accompany the application.

This notice of your license expiration is sent for your convenience. The responsibility for submission of a properly completed application to assure timely license renewal remains with the licensee, further notices may not be forthcoming.

Sincerely,

_____
Bureau of Radiation Control

Enclosure

GLOSSARY 0314 CALL NUMBER 9

DATE

CERTIFIED MAIL
RETURN RECEIPT REQUIRED

LICENSEE ADDRESS

Dear _____:

This refers to the activities authorized by Radioactive Material License No. _____.

Based on the review of your radioactive material license, it appears that certain of your activities were not conducted in full compliance with Bureau requirements. The violations which occurred are described in the enclosed Notice.

Sincerely,

Larry F. Anderson, Director
Bureau of Radiation Control

Attachment

BUREAU OF RADIATION CONTROL
NOTICE OF VIOLATION

LICENSEE
ADDRESS

License No. _____

During a review of your radioactive material license on _____, a violation was identified. In accordance with Utah Radiation Control Rules, R447-14, "Violations and Escalated Enforcement," the particular violation is set forth below:

R447-22-37(2) of the Utah Radiation Control Rules states:

> "In any case in which a licensee, not less than thirty days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Bureau."
>
> Contrary to this, radioactive material license number UT _____ issued to _____, expired on _____.

To resolve this issue you must do the following:

1. Store all radioactive material.

   If adequate storage facilities are not available, then the material should be transferred to an authorized recipient until a new license has been issued.

2. Submit a letter within 30 days to the Bureau stating the following:

   a. Make the following commitments in writing.

      (1) To store or transfer the radioactive material you now possess.

      (2) State that you will not use any of the stored radioactive material until a new license has been issued.

R447-18-11(1)(d) requires that you post a copy of this Notice in a conspicuous place. Should you have any questions concerning this Notice please contact us at 538-6734.

Sincerely,

Larry F. Anderson, Director
Bureau of Radiation Control

Dated at Salt Lake City, Utah
this _____th day of _____, 19____.

y
!The following statement shall be added to Standard Notice of Violation glossary 314 call number 9 if the application has not been signed by the appropriate individual.!

Paragraph R447-22-37(2) states, "In any case in which a licensee not less than thirty days prior to expiration of the existing license has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Bureau."

Contrary to this rule, an application for renewal of license number _____ was received by the Bureau of Radiation Control on _____ without the appropriate required signature on the application.

z
!The following statement shall be added to Standard Notice of Violation glossary 314 call number 9 if the application is not accompanied by the appropriate fee.!

Paragraph R447-70-5(1) of the Bureau of Radiation Control Rules states, "Each application for machine registration or radioactive material licensing for which a fee is prescribed, shall be accompanied by a remittance in the full amount of the fee. No application will be accepted for filing or process prior to payment of the full amount specified."

Contrary to this rule, an application for renewal of license number _____ was received by the Bureau of Radiation Control on _____ without the required f accompanying the application.

Revision 2
December 1977

U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 3.11

DESIGN, CONSTRUCTION, AND INSPECTION OF EMBANKMENT RETENTION SYSTEMS FOR URANIUM MILLS

A. INTRODUCTION

Each licensee who processes or refines uranium ores in a milling operation is required by §20.1 of 10 CFR Part 20, "Standards for Protection Against Radiation," to make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable, taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety. In addition, 40 CFR Part 190, "Environmental Radiation Standards for Nuclear Power Operations," requires that the maximum annual radiation dose to individual members of the public resulting from fuel cycle operations be limited to 25 millirems to the whole body and to all organs except the thyroid, which must be limited to 75 millirems. Liquid and solid wastes (tailings) generated in the uranium milling operation contain radioactive materials in excess of the discharge limits and are generally confined by an embankment retention system.

This guide describes some engineering practices and methods generally considered satisfactory for the design, construction, and inspection of earth and rockfill embankments used for retaining uranium mill tailings. They result from review and action on a number of specific cases and reflect the latest general approaches to the problem that are acceptable to the NRC staff. If new information that may be developed in the future results in alternative methods, such methods will be reviewed by the staff to determine their acceptability. Guidance on operation and abandonment of the retention system is presented in separate guides. *

B. DISCUSSION

The milling of uranium ores results in the production of large volumes of liquid and solid wastes (tailings). These tailings are usually stored behind man-made retaining structures, following the practice of the non-uranium mining industry. The design and construction of tailing retention structures have in the past been based largely on mining experience, with little use of design concepts. These empirical approaches resulted in various mining dam mishaps and failures (Refs. 1 and 2). The failure of Buffalo Creek Dam in West Virginia even resulted in the U.S. Congress quickly passing a national dam safety law affecting all water-impounding structures in excess of either 25 feet in height or 50 acre-feet in impoundment capacity (Ref. 3).

Uranium mill tailings, unlike most non-uranium mine tailings, contain concentrations of radioactive materials in excess of the allowable discharge limits (Ref. 4). Furthermore, the most significant radioactive element in the tailings is radium-226, which has a half-life of about 1600 years (Ref. 5). Therefore, it is necessary to confine those tailings to prevent or control their release to the environment not only during the operating life of the mill, but also for genera-

* Lines indicate substantive changes from previous issue.

tions after milling operation has ceased. The embankment, foundation, and abutments need to be stable under all conditions to prevent the uncontrolled release of the retained water or semifluid tailings. Seepage from the tailing pond, which contains dissolved radium and other toxic substances (Ref. 5), needs to be controlled under normal and severe operating conditions to prevent the possibility of unacceptable contamination of the groundwater or nearby streams. Wind and water erosion of the tailings needs to be prevented during and after the milling operation.

Obviously, factors pertaining to safety, contamination, and environmental damage determine the basic requirements in planning and constructing retention systems. To achieve the basic requirements, the design must be based on a thorough understanding of both the geotechnical problems involved and the requirements of the milling operation.

The latest advances in geotechnical engineering, together with engineering experience and knowledge available in the field of water storage dams, can be used in the design and construction of retention dams. The basic concepts of conventional water storage dams can be suitably modified to produce economical designs that will ensure the stability of the retention system and minimal contamination.

1. GENERAL PLANNING AND DESIGN CONSIDERATIONS

Because the prime functions of the retention system are to store radioactive solids and to provide temporary storage of contaminated water for clarification and evaporation, it is important that the system be designed and constructed to remain stable for its intended life. It must provide the required storage at any given time, and it must provide sufficient control of seepage to prevent unacceptable contamination of adjacent land, waterways, and groundwaters. It must also provide effective means to prevent wind and water erosion.

Stage construction with the freeboard maintained sufficiently above the storage level may be considered. The use of coarse tailings as embankment fill materials is not desirable because the tailings contain radioactive materials that may cause unacceptable environmental impacts.

Detailed site conditions, including climate, hydrology, geology, and seismology, need to be assessed and their impact evaluated. Detailed knowledge is needed of such physical and mechanical properties of foundation and embankment materials as classification, shear strength, consolidation, permeability, sedimentation, compaction, piping and cracking susceptibility, and wind-water erosion characteristics. The chemical qualities of the tailings and slurry must be assessed to determine if a water-collecting system is needed to prevent unacceptable downstream contamination resulting from seepage or surface water runoff.

Subsurface investigations at the site of the retention system and at possible borrow areas need to be adequate to determine the suitability of the foundation and abutments, the requirements of foundation treatment, and the availability and characteristics of embankment materials. The investigations should cover classification, physical and chemical properties, location and extent of soil and rock strata, and variations in groundwater conditions.

The foundation conditions must be determined to assess the adequacy of subsurface materials to support the dam without failure and without excessive total or differential settlement. The permeability of foundation soils and rocks must be ascertained to estimate the amount of seepage, piping potential, and, if necessary, the methods of seepage control. The availability of suitable borrow material for dam construction must be assessed, taking into consideration the construction sequence and schedule.

2. DESIGN ANALYSIS

It is important that design analysis consider stability, settlement, seepage, and hydrologic analyses. Specifically, the design needs to ensure that retention dam failure would not occur. Historical records (Refs. 6–9) indicate that most failures associated with earth or tailing dams are caused by overtopping by flood waters, erosion, piping in either the dam or the foundation, collapse of the dewatering conduit, foundation failure, slope failure, or liquefaction.

2.1 Hydrologic Analyses

There will always be some catchment area contributing runoff into the tailing retention system. This may vary from the area of the system itself to a substantial area incorporating the drainage area of streams entering the valley across which a retention dam is constructed. Substantial runoff volumes and flows can result from heavy precipitation or snowmelt over relatively small catchment areas.

The maximum runoff used in the design is usually called the Spillway Design Flood (SDF), representing the largest flood that need be analyzed, regardless of whether or not a spillway is provided. The magnitude of the SDF (flood volume, peak flow, etc.) as adopted in the United States for the past 30 years is equal to that of the Probable Maximum Flood[1] at the

[1] The Probable Maximum Flood (PMF) is defined as the flood that may be expected from the most severe combination of critical meteorologic and hydrologic conditions that are reasonably possible in the region.

site of the dam. Methodology to estimate the Probable Maximum Flood is available in Regulatory Guide 1.59, "Design Basis Floods for Nuclear Power Plants," and other publications (Refs. 10 and 11).

For small retention dams built on isolated streams in areas where failure would neither jeopardize human life nor create damage to property or the environment beyond the sponsor's legal liabilities and financial capabilities, less conservative flood design criteria may be used in the design. However, the selection of the design flood needs to be at least compatible with the guidelines set forth by the Corps of Engineers (Ref. 12).

If decant or other reclaim systems have not been designed specifically to pass the design flood, other measures need to be taken. Those other measures may be one or a combination of the following:

a. Storing the whole volume of flood runoff. Sufficient freeboard should always be available to provide the necessary storage capacity without overtopping the dam.

b. Providing a spillway or diversion channels to convey runoff water safely past the dam.

Because of the toxic nature of the impounded material, a is preferred.

Determination of the freeboard necessary at any time to store flood runoff will require information on pond storage versus elevation, anticipated embankment settlement versus time, and the effective height of wind-generated waves. Procedures for determining the minimum freeboard are presented in Reference 10. It is important that the embankment construction schedule ensure that this required freeboard is always available.

Adequate slope protection is needed to guard the embankment against wind and water erosion, weathering, and ice damage. Methods for protecting slopes include dumped riprap, precast and cast-in-place concrete pavements, bituminous pavement, soil cement, sodding, and planting. The necessary upstream slope protection depends on the expected wind velocity and duration and the size and configuration of the reservoir at the water-surface elevation. The necessary downstream protection depends on the expected erosion of surface runoff and wind erosion. References 10 and 13 provide methods and criteria for the selection and design of slope protections.

2.2 Stability Analysis

Slope failure occurs when an outer portion of an embankment slides downward and outward with respect to the remaining part of the embankment. The slide generally occurs along a fairly well-defined slip surface. Stability analyses involve comparing the shearing stresses along potential failure surfaces with the available shearing resistance along those surfaces. The ratio of the available shear strength to developed maximum sheer stress gives the factor of safety.

2.2.1 Methods of Stability Analysis

2.2.1.1 Static Stability Analysis

There are many methods using the limiting equilibrium approach. Detailed discussion can be found in various publications (Refs. 14–16). These methods may be conveniently grouped into three categories:

a. *Friction Circle Method.* This method considers the entire sliding block as a rigid free body and makes assumptions regarding the distribution of normal stresses along the failure surface. This method can only be used to evaluate failure surfaces that are circles or single straight lines. The logarithmic spiral method is a different version of this method.

b. *Method of Slices.* This method divides the free body into many vertical slices, and the equilibrium of each slice is considered. The best known and most widely used versions of this method are the Swedish Circle Method, Modified Swedish Method, Simplified Bishop Method, and Morgenstern-Price Method.

c. *Wedge Method.* This method is used whenever the failure surface can be satisfactorily approximated by a series of straight lines—usually two or three lines.

The method of slices offers the best approach for obtaining a reasonably accurate solution for any shape of failure surface (Refs. 17 and 18). While the friction circle method can provide solutions in homogeneous soil, it is difficult to apply these approaches with confidence when the soil is stratified or zoned. The wedge method can provide reasonable solutions for situations where the failure surfaces are composed of straight lines.

Computer solutions to the method of slices have been developed (Ref. 18). By using computers, many more assumed conditions and failure surfaces can be tried. The effects of possible variations in material properties can also be evaluated. The computed results need to be checked with respect to their reasonableness and compatibility with the design procedures and criteria.

2.2.1.2 Seismic Stability Analysis

In areas where embankments are subjected to seismic disturbances, analyses should be made of the seismic effects on the dams. Seismic vibrations can cause liquefaction of saturated or nearly saturated loose sands and sensitive silts (Ref. 1). The dynamic shearing stresses induced during the seismic events can cause excessive deformation or distortion of the embankment—even shear failure (Refs. 19 and 20).

Seismic stability analyses of embankment dams are conventionally made using pseudostatic methods (Ref. 21). In this approach, the stability of a potential sliding mass is determined as for static loading conditions, and the effects of an earthquake are taken into account in the computation by including an equivalent horizontal force acting on the potential sliding mass. The horizontal force representing earthquake effects is expressed as the product of the weight of the sliding mass and a seismic coefficient. The value of the seismic coefficient is normally selected on the basis of the seismicity of the region in which the dam is to be constructed.

During earthquakes, large cyclic inertia forces are induced in embankments. In certain zones of an embankment, the inertia forces may be sufficiently large and may occur a sufficient number of times to cause permanent displacements. Procedures for estimating the magnitude of these displacements have been proposed by Newmark (Ref. 22) and by Goodman and Seed (Ref. 19). Both of these procedures presume a knowledge of the time-history of the inertia forces acting on an embankment during the earthquake. These approaches are more involved than the conventional methods and have been used successfully to predict the surface displacements of embankments of dry cohesionless soils. However, for soils in which pore pressure changes as a result of the shear strains induced by the earthquake, determination of appropriate values of the yield acceleration becomes difficult.

In dealing with saturated cohesionless soils, the dynamic analysis procedures developed by Seed (Ref. 23) provide a basis for assessing the stability and deformation of the embankment during earthquakes. This type of analysis may be used to predict the development of the liquefaction zone and the anticipated movements, deformation, and stability of the embankment and its foundation. However, good engineering judgment based on adequate data must be exercised in the selection of soil characteristics for use in the analyses, in the detailed steps followed to conduct the analyses, and in the evaluation of the results obtained.

A detailed discussion and applicable guidelines for seismic analysis and design of tailing dams can be found in Reference 24.

2.2.1.3 Liquefaction Potential Evaluation

It is important that the possibility of liquefaction of foundation soils be evaluated by means of "state-of-the-art" procedures involving seismological and geological investigations. The objective of such evaluations is to establish earthquake design parameters for use in the analyses and the dynamic testing of materials. Procedures currently used for evaluating liquefaction potential are based on either comparing the past experience with similar soil deposits supplemented by laboratory tests or using detailed ground response analyses combined with dynamic laboratory testing. Past experience provides the most useful guidance on the probable performance of similar soil deposits, while the ground response method provides a means for considering the effects of the amplitude and time history of the earthquake ground motions, the in-situ soil characteristics, the overburden pressure, and the groundwater conditions.

2.2.2 Loading Conditions and Factor of Safety

A tailing dam and its foundation are subjected to shear stresses imposed by the weight of the dam and by the filling of the pool, seepage, or earthquake forces. The cases for which stability analyses are necessary are

a. *End of construction*. Analyses of the upstream and downstream slopes are needed for the end of construction conditions if the embankment and its foundation are composed partially or entirely of impervious soils. The unconsolidated undrained (UU) shear strength should be used in the analyses for slow-draining soils, while consolidated drained (CD) shear strength should be used for free-draining soils where excess pore pressures would not develop.

b. *Partial pool with steady seepage*. Analyses of the upstream slope are needed for several intermediate pool stages with corresponding steady seepage conditions. The analyses account for reduction in effective normal stresses where pore water pressures that developed during construction or filling are not dissipated before the subsequent partial pool condition. The lower strength from either the consolidated undrained (CU) shear test or consolidated drained (CD) shear test is used in the analyses. The minimum factor of safety should be determined as a function of pool elevations.

c. *Maximum storage pool with steady seepage*. This condition may develop and may be critical to downstream slope stability. A flow net would be helpful in determining the phreatic line and seepage forces. Shear strength selection should be the same as for the partial pool with steady seepage condition.

d. *Earthquake*. In areas subjected to seismic shocks, appropriate earthquake forces need to be added onto the previous loading conditions in the stability analyses.

The use of a factor of safety in stability analyses should allow sufficient margin for variations between the parameters used in design and those existing in the field and consideration of the limits of strains. Many soils undergo relatively large plastic strains as the applied shear stresses approach the shear strength of the soil.

The consequence of a failure, the tolerable limits of strains, and the degree of confidence in engineer-

ing parameters used in the analyses all need to be considered in choosing the factor of safety. The minimum factor of safety suggested in the regulatory position of this guide presumes that the stability analysis has been sufficient to locate the critical failure surface and that parameters used in the analysis are known, with reasonable certainty, to be representative of actual conditions of the dam and its foundation. Otherwise, higher factors of safety would be required.

2.2.3 Settlement Analyses

If the foundations beneath an embankment consist of layers of compressible soils or weathered rock or if the bedrock profile is very irregular, differential settlements could result from uneven loading or variable thicknesses in the compressible site conditions. These differential settlements may cause longitudinal or transverse cracks in the dam that could lead to subsurface erosion and dam failure by piping.

The magnitude of the anticipated settlement can be estimated from the results of laboratory consolidation tests on samples recovered from the compressible foundation strata and remolded embankment materials. The rate of settlement can also be estimated. However, the potential error in estimating the time for settlement to occur is appreciable, since settlement is influenced by soil drainage that is controlled by minute geological details that may not be detected during the foundation investigation. All predictions on the rate and magnitude of settlement and the change in pore water pressures need to be checked by field instrumentation. Predictions based on laboratory data can be modified by actual measurements to provide reasonably accurate long-term estimates.

If compressible soils are thick, it may be necessary to design the dam to absorb the anticipated differential settlements. If considerable total settlement is expected, the dam must be built higher to allow for the settlement.

2.2.4 Seepage Analyses

Seepage analyses evaluate the effects of seepage on the stability of the tailing dams and the rate of seepage through and beneath the dam and basin area. It is important that seepage pressures be controlled so that quick conditions and piping do not develop. Special design features such as impervious cores, cutoffs, impervious liners, a secondary collection system, etc., are needed to maintain the quality and quantity of seepage from the retention system within tolerable limits of water supply and pollution control requirements.

Seepage analyses—usually based on the steady flow of an incompressible fluid through a porous medium—may use the graphical method of plotting flow nets, electric analogs, model studies, or mathematical solutions by digital computer using either finite-element or finite-difference methods. The graphical method of plotting flow nets is economically and easily performed, and it gives sufficiently accurate results for many seepage problems.

3. CONSTRUCTION METHODS

Construction methods for mill tailing dams are closely related to the planning and operation of the mill. Where a tailing embankment is constructed in a single stage of natural borrow materials or overburden and waste rock, conventional procedures for earth and rock-fill dams can be used.

Where a tailing dam is constructed in stages, one of the following three methods is used: (a) upstream method, (b) downstream method, or (c) centerline method.

The upstream construction method is the oldest used by the mining industry and is a naturally developed procedure for disposing of the tailing as economically as possible. An initial starter dike is constructed at the downstream toe of the ultimate dam with borrow materials. The crest of the dam is raised by placing fill materials in successive dikes located on the upstream side of the initial starter dike. The centerline of the embankment crest is shifted toward the upstream pond area as the height of the dam increases. The downstream toe of each subsequent dike is supported on the top of the previous dike, with the upstream portion of the dike placed over finer tailings (slimes) within the impoundment. These slimes, placed hydraulically, have a relatively low shear strength and remain in a loose and saturated state for many years after deposition (Ref. 25). As the height of the dam increases, the potential failure is located at an increasingly greater distance from the downstream face and through the slimes. As a result, the outside shell contributes less to stability as the height increases. The retained slimes are sufficiently loose and saturated that they could be liquefied to cause the failure of the dam if subjected to seismic shock or blasting.

With the downstream construction method, an initial starter dike is constructed at the upstream toe of the ultimate dam. The crest of the dam is raised by placing fill materials in successive dikes located on the downstream side of the starter dike. The centerline of the dam crest is shifted downstream as the dam is raised. Each subsequent stage of dike construction is supported on the top of the downstream slope of the previous section. All of the embankment section lies ouside the boundaries of the sediment tailings. Materials incorporated in subsequent stages of the embankments may consist of the coarse mine waste or borrow materials from nearby pits. Downstream construction permits controlled placement and compaction to achieve higher shear strength. It also permits the incorporation of drainage facilities to control the piezometric pressures within

the embankment. Thus the dam can be designed and subsequently constructed to whatever degree of competency may be required, including resistance to seismic and blasting shocks.

The centerline method is intermediate between the previous two construction methods. The crest of the embankment is maintained in approximately the same horizontal position as the embankment is raised to its final height. The dam is raised by spreading and compacting successive layers of materials on the crest, on the upstream shoulder, and on the downstream slope. The centerline method permits the downstream half of the tailing dam to be designed and constructed to conventionally acceptable engineering standards; however, certain portions of upstream slopes rest over the slimes and are therefore vulnerable to slope failure and seismic liquefaction.

These three construction methods lead to substantially different embankment cross sections and produce different embankment material characteristics. Consequently, the embankment stability conditions are affected. In the upstream and centerline methods of construction, the stability of the ultimate dam is dependent, to a large degree, on the shear strength characteristics of tailings deposited upstream of the dam. The shear strength is governed by the gradation and density of the solids, the consistency of the slurry, and the distribution of the pore water pressures within the deposit. When initially deposited, the tailings have very low shear strength. The strength theoretically increases with time as drainage and consolidation take place under the weight of overlying materials. However, because of the very fine gradation of the tailings and the random nature of deposition, large variations in permeability and pore water pressure exist within the tailings, and the strength may not increase adequately to ensure the stability of the final slope (Ref. 26).

Downstream construction is the only method wherein all embankment sections lie outside the tailing boundaries, thereby permitting controlled placement and compaction of fill and incorporation of drainage facilities. Thus, for a given height and a given downstream fill slope, a tailing dam constructed using the downstream method will have a higher factor of safety than a tailing dam constructed by either the upstream method or the centerline method.

Because the most important purpose of the tailing dam structure is to contain the radioactive waste materials and the performance of hydraulically constructed dams and tailing dams has been unsatisfactory (Refs. 6, 8, and 27), the downstream method appears to be the best of the stage construction methods to ensure the safety function of the tailing dams, especially in seismically active areas.

4. INSPECTION AND MAINTENANCE

Different conditions can develop throughout the whole active life of the retention system and could include unanticipated seepage conditions and changes in material characteristics. Such changes can drastically change the conditions governing the stability of a dam from those provided for in the original design. Therefore, a continuous program of inspection of the retention system is needed, beginning with the start of construction, through the tailing disposal, and continuing after abandonment of the completed system.

The main objectives of such a program are to ascertain:

a. Whether the dam and its foundation are behaving as anticipated in the design, whether there are any unusual movements, settlements, cracks, erosions, sloughs, or leakages, and whether the waste and borrow materials being placed in the dam have the characteristics assumed in the design;

b. Whether the tailing pond levels are rising as anticipated and whether the rate of dam construction is sufficiently rapid to keep the crest above rising pond; and

c. Whether embankment drainage is adequate, whether the capacity of diversion channels is adequate to pass experienced and anticipated runoffs, whether embankment soil is becoming saturated by seepage, whether piping or subsurface erosion is occurring in the tailing dam, and whether there is any unusual release of radioactive materials.

It is necessary that inspection be performed on a regular basis and that it include visual inspection of the abutments. A checklist similar to that used in water retention dams may be used to help the inspector in performing such a visual inspection.

Instrumentation needs to be installed to monitor dam and basin performances at regularly scheduled intervals. Instruments commonly used include piezometers to measure hydrostatic and pore pressure levels; weirs or flumes to measure seepage flows; wells to permit monitoring of water quality; and slope indicators, inclinometers, and settlement points to measure horizontal and vertical movements. The instrumentation should be simple, robust, rugged, reliable, and easy to read, repair, and maintain. It is important that recorded data from instrumentation and inspections be evaluated by competent personnel with delegated authority to take prompt action if remedial treatment is needed to maintain the safe operation of the retention system.

C. REGULATORY POSITION

The following criteria reflect the latest general approaches approved by NRC.[2] Information related to the investigation, engineering design, proposed construction, instrumentation, and performance of the retention system should be presented in accordance with the applicable portion of Section 2.5.6 of Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants." If an applicant wishes to use new information that may be developed in the future or to use an alternative method, NRC will review the proposal and will approve its use, if it is found acceptable.

1. BASIC DESIGN CRITERIA

a. Stability of the retention system, including the tailing dam, foundation, and abutments, should be ensured under all conditions of construction and operation.

b. The magnitude of total and differential settlement should be within tolerable limits that will not result in harmful cracking and dam instability.

c. Seepage through the embankment, foundation, abutments, and basin area should be controlled to prevent excessive uplift pressures, piping, sloughing, and erosion of materials by loss into cracks, joints, and cavities. The quality and quantity of seepage should be limited to the extent that the concentration of radioactive materials and other toxic materials at the site boundary is within the limits specified in applicable Federal and State regulations.

d. Freeboard should be sufficient at all times to prevent overtopping by wind-generated waves and should include an allowance for settlement of the foundation and dam. Adequate slope protection should be provided for the embankment against wind and water erosion, weathering, and ice damage.

e. Either the surcharge capacity of the retention system should be sufficient to store runoffs over its service life or there should be an emergency discharge capacity capable of passing the probable maximum flood. The emergency discharge capacity may be obtained by constructing a spillway or by other means. The surcharge capacity should be adequate to store a probable maximum flood series[3] preceded or followed by a 100-year flood, assuming a pool elevation equivalent to the average annual runoff.

2. METHODS OF ANALYSIS

a. The probable maximum flood should be determined in accordance with applicable portions of Regulatory Guide 1.59, "Design Basis Floods for Nuclear Power Plants."

b. The static stability of the embankment should be analyzed using commonly accepted detailed stability methods. Appropriate static soil and rock properties established on tested representative samples over anticipated in-situ and placement conditions should be used in the analyses. Results of a manual check on computer stability analysis results should be presented to illustrate adopted design procedures and criteria.

c. Conventional pseudostatic analysis may be considered acceptable if the seismic coefficient appropriately reflects the geologic and seismologic conditions of the site and if the materials are not subject to significant loss of strength under dynamic loads. Liquefaction potential and the dynamic stability of the tailing dam and foundation should be assessed using appropriate state-of-the-art methods. The extent of the required dynamic analyses will be determined in accordance with Reference 24. Appropriate dynamic material properties established on representative materials through adequate field and laboratory testing should be used in the analyses.

d. The loading conditions to be evaluated in dam stability analyses and corresponding minimum factors of safety are:

Loading Condition	Minimum Factor of Safety	Shear Strength
End of construction	1.3	UU and CD
Partial pool with steady seepage	1.5	CU or CD
Maximum pool with steady seepage	1.5	CU or CD
Earthquake (in combination with the above conditions)	1.0[4]	

e. The rate and magnitude of settlement should be estimated on the basis of appropriate laboratory test results.

f. Seepage analyses may be based on a graphical method, model studies, or mathematical solutions using appropriate soil and rock parameters.

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[2] The Nuclear Regulatory Commission announced in the *Federal Register* of June 3, 1976, (41 FR 22431) its intent to prepare a generic environmental impact statement (GEIS) on uranium milling operations. Management practices for uranium mill tailings may be subject to revision in accordance with the conclusions of that statement and any related rule making.

[3] Probable maximum flood series as used herein comprises two floods: the Probable Maximum Flood and the flood equivalent to about 40% of the PMF and about 3 to 5 days prior to the occurrence of the main flood.

[4] Factor of safety is for pseudostatic stability analysis. In addition, liquefaction and excessive deformation should be assessed

[5] Use shear strength for case analyzed without earthquake.

3. CONSTRUCTION METHODS

a. Conventional acceptable engineering practices of construction control for water retention dams (e.g., controls on foundation preparation, suitability of materials, proper placement, field moisture, and density) should be used for mill tailing dams. Where a tailing dam is raised in stages, the downstream construction method is preferred. Provision should be made to limit the concentration of radioactive and other toxic materials released from seepage and wind-water erosion to within the limits specified in 10 CFR Part 20, 40 CFR Part 190, and applicable State regulations.

b. The upstream and centerline construction methods will be acceptable only if extensive explorations and testing reveal the extent and characteristics of deposited tailings to have adequate strength under static and dynamic loading conditions for the stability and support of the added materials.

4. INSPECTION AND MAINTENANCE

a. A detailed systematic inspection and maintenance program should be established to detect and repair damage that might tend to lessen the integrity of the retention system. Generally, visual inspections performed on a regular basis and supplemented by adequate instrumentation are acceptable. The safety inspection guidelines (Ref. 12) for earth dams set forth by the Corps of Engineers in response to the National Dam Safety Act should be used to develop a detailed checklist for performing field inspections. In addition, radiometric and water quality surveys should be included in the program.

b. Instrumentation should be installed in the dam or its foundation to monitor changes that might be critical to dam stability or seepage conditions. Generally, instruments should be installed to measure piezometric levels, seepage flows, water quality, and embankment movements. The extent to which such instrumentation should be installed will be evaluated on a case-by-case basis.

c. Results of inspection and instrumentation programs should be evaluated by competent and experienced engineers who have delegated authority to take prompt effective actions when necessary. Inspection and evaluation reports should be kept at the site and be available for staff review.

d. The inspection and maintenance program should start at the beginning of construction and continue at least through the operation.

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DATED: MAY 7, 1998 SIGNED BY: PAUL H. LOHAUS

ALL AGREEMENT STATES
OHIO, OKLAHOMA, PENNSYLVANIA

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-98-040)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION..... XX *GUIDANCE FOR REPORTING MATERIAL EVENTS*

PROGRAM MANAGEMENT INFORMATION....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION.....

Supplementary information: Enclosed is Office of State Programs (OSP) Procedure SA-300, Reporting Material Events, and it's Appendix, a revised "Handbook on Nuclear Material Reporting in the Agreement States." The "Handbook" is a final version of the handbook previously provided to you for use and comment by OSP in March 1995 (SP-95-036). The procedure and handbook provide guidance for Agreement State reporting of material events to the NRC. SA-300 and the "Handbook" contain procedures for providing NRC:

(1) Initial notification of the occurrence of a significant or routine event involving nuclear material (Section 1.0, of the "Handbook," pp.1-3).

(2) Pertinent follow-up information (results of any evaluations or investigations, dose assessments, leak tests, equipment assessments, inspection reports, corrective actions, etc.); and any additional information on technical or regulatory action through resolution and close out of the event (Sections 1.3 and 1.4, pp. 4-6).

(3) Guidance on electronic reporting of event information to the "Nuclear Materials Events Database" (NMED) and on written (hard copy) reporting through submission of Agreement State licensee event reports to the Director, OSP (Sections 1.3 and 1.4, pp. 4-6).

Guidance covering recent revisions to Title 18 of the Criminal Code, that expands the role of the Federal Bureau of Investigations (FBI) in the criminal use of radioactive material, and guidance on Agreement State notification to the FBI regarding specific categories of material events is contained in All Agreement States Letter SP-98-038. An Errata Sheet is also enclosed which adds the FBI guidance to the Reference Manual Section of the "Handbook."

For purposes of compatibility, the reporting of incidents and events involving the use of nuclear material by an Agreement State to NRC is now mandatory under the Policy Statement on Adequacy and Compatibility of Agreement State Programs approved by the Commission on June 30, 1997. The quality, thoroughness, and timeliness of material event reporting by the

Agreement States to NRC, including Agreement State event information contained in NMED, will be reviewed during the annual meetings with Agreement States between the Integrated Materials Performance Evaluation Program (IMPEP) reviews, and will be evaluated during IMPEP reviews under the Common Performance Indicator, Response to Incidents and Allegations. We hope the enclosed procedure and handbook will be of assistance to you and your staff in the reporting of event information and will help in maintaining a national database of NRC and Agreement State information.

Information requested in the Handbook has been approved by OMB 3130-0178, expiration date June 30, 2000. If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

If you have any questions regarding this correspondence, please contact me or the individual named below.

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Paul H. Lohaus, Deputy Director
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Enclosures:
As stated

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Appendix
to
OSP Procedure SA-300, Reporting Material Events

Handbook on Nuclear Material Event Reporting in the Agreement States

OSP Procedure Approval

Issue Date: February 25 , 1998

Expiration Date: February 25, 2001

Richard L. Bangart
Director, OSP Richard L Bangart *Date: February 25, 1998*

Paul H. Lohaus
Deputy Director, OSP Paul H Lohaus *Date: February 24, 1998*

Patricia M. Larkins
Procedure Contact, OSP Patricia M. Larkins *Date: February 20, 1998*

NOTE

The OSP Director's Secretary is responsible for the maintenance of this master copy document as part of the OSP Procedure manual. Any changes to the procedure will be the responsibility of the OSP Procedure Contact. Copies of OSP procedures will be distributed for information.

ABSTRACT

The review and evaluation of operational event information identifies safety-significant events and concerns, and their causes. This handbook has been developed to provide information to the staff of the Agreement States that are responsible for the preparation of event reports for incidents and events involving the use of nuclear materials that have occurred in their State. Reporting of Agreement State material events to NRC is mandatory for purposes of compatibility. The handbook describes the procedure to be followed in reporting significant and routine material events to NRC. Guidance is provided on what information should be reported, the level of detail, and where to report. Procedures for identifying and reporting Abnormal Occurrences (AOs) are also included. The objective of the handbook is to:

- Improve technical information
- Standardize format
- Ensure consistency
- Facilitate information retrieval

It has been divided into two sections and one appendix.

Section I - Event Reporting Process, describes the process for reporting significant and routine incidents and events involving the use of nuclear materials that have occurred in the Agreement States. Information is provided on reporting material events to the Nuclear Materials Events Database (NMED).

Section II - Abnormal Occurrence Guidelines and Criteria, describes the process for identifying and reporting material events that reach the level of an abnormal occurrence (AO) that have occurred in the Agreement States.

Appendix - contains a glossary of terms and listing of reference manuals and information.

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SECTION II - Abnormal Occurrence Guidelines and Criteria

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PREFACE

The regulatory authority and policies governing the Agreement State program are presented below.

Regulatory Authority

Section 274 of the Atomic Energy Act provides a statutory basis under which the Federal government may relinquish portions of its regulatory authority to the States and authorizes and directs NRC to cooperate with the States in the formulation of standards to protect employees or the general public against hazards of radiation and to assure that State and Commission programs will be coordinated and compatible. Pursuant to the "Act" and the Energy Reorganization Act of 1974, as amended, the NRC evaluates material events and abnormal occurrences in licensed facilities. In addition, the Energy Reorganization Act requires NRC to provide to Congress on an annual basis, information on significant events that meet the abnormal occurrence criteria.

Regulations have been established that require material licensees to monitor and control activities that can lead to the exposure of employees or the general public to radiation. For purposes of compatibility the reporting of incidents and events involving the use of nuclear materials by the Agreement States to NRC is now mandatory. The information from reports of medical misadministrations, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by both the NRC and the Agreement States is invaluable in assessing trends or patterns and inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs.

SECTION I

Event Reporting Process

1.0 EVENT REPORTING PROCESS

1.1 Introduction

Procedures for the Agreement States to report to NRC information on material events that have occurred in their State are presented below. Guidance is provided on electronic reporting of event information to the "Nuclear Materials Events Database (NMED)." Guidance is also provided on hard copy reporting (written reports) of Agreement State licensee event reports to the Director, OSP. When submitting an event report, enough information about an event should be provided so that NRC and Agreement States can evaluate the event in terms of safety significance, long-term generic implications, and as a possible candidate for the "Abnormal Occurrence Report to Congress."

- Reportability Determination

  Agreement States should receive event information from Agreement State licensees that is compatible with the information provided by NRC licensees under applicable, compatible Agreement State regulatory reporting requirements. Table 1.1 of this guide contains a listing of NRC regulatory reporting requirements that are the basis for equivalent reporting requirements in Agreement State regulations. Table 1.2 provides further clarification by including a brief description of the specific reporting requirement. These tables begin on page 7 of the "handbook."

- How often are material events reported to NRC?

  Significant events (requiring 24 hour or less notification by an Agreement State licensee) should be reported promptly to NRC by an Agreement State, within 24 hours or less of notification by an Agreement State licensee. Routine events (requiring 5, 15, 30 or 60 day notification by an Agreement State licensee) should be reported within one month of notification of the occurrence of an event by an Agreement State licensee, member of the public, or other agency. Follow-up reports through closeout of the event should be provided within 30 days of receipt from an Agreement State licensee. Information on State action, e.g., investigation results or enforcement actions may be requested by NRC on an ad hoc basis.

- Voluntary Reporting

  The Commission encourages voluntary reporting of an occurrence that actually happened (event) or something that may happen (condition) that does not meet the regulatory reporting criteria that the State believes might be of safety significance or of generic interest or concern, or involves media interest.

- Event Report Number

All event reports (significant and routine) should have a report identification number. For each agency in your State, Agreement States should assign an event report number to the preliminary or initial notification report and any follow-up reports, with the "Agreement State Identification No.," consisting of the State agency ID, year, and a sequentially assigned ID number, e.g., (NY-98-001), (NYC-98-001), (NYL-98-001), (NYE-98-001), (TX-97-001), (TXNR-98-001), (GA-98-001), (NE-98-001), (CA-98-001). NOTE: The Agreement State ID# field in NMED can accommodate up to four characters for the State or agency identifier. The "Agreement State ID No." should be specified by the State for all telephone, electronic or written notification involving each specific event. This will ensure proper coding in NRC's internal Document Control System (DCS) and that all information on a given event is contained in one record in NMED. It will also aid in simplifying the search for all of a State's information in the NMED database.

- The Nuclear Materials Events Database (NMED)

All material event information is maintained in the Nuclear Materials Events Database (NMED) by the NRC Office for Analysis and Evaluation of Operational Data (AEOD). NMED contains NRC's historical collection of information on the occurrence, description, and resolution of events involving the use of byproduct nuclear material in the United States. The database is maintained by NRC through a contractor, Idaho National Engineering and Environmental Laboratory (INEEL). NMED accommodates the sharing of material event data submitted by Agreement States and NRC licensees. INEEL enters material event information received from the Agreement States via PC diskette, e-mail file, or in writing into NMED. Agreement States will receive monthly updates of data directly from INEEL in a format previously designated by the State. The monthly update should be reviewed to ensure that each State's event information has been properly included. A copy of the NMED software, and the accompanying NMED Coding Manual, have been provided to all Agreement States.

1.2 Reporting Significant Events (requiring immediate or 4-24 hour notification by an Agreement State licensee)

a. Report Significant Events to the NRC Operations Center.

b. Agreement States should report to the NRC, within 24 hours or less of notification by an Agreement State licensee, significant events requiring prompt notification as determined under applicable Agreement State regulations. (For reference, NRC reporting requirements for significant events are presented in Table 1.1 and 1.2 on pages 7 and 9)

c. Agreement States should report the events by telephone or FAX to the NRC Operations Center, telephone No. (301) 816-5100, (301) 951-0550, and FAX (301) 816-5151.

The following information should be provided, if known:

1. Event Report Identification No.
2. License No.
3. Licensee
4. Event time, date, location
5. Event type (e.g., misadministration, lost source, overexposure, etc.)
6. Any notifications, i.e., other agencies, patient, press release, etc.
7. Event description: release, isotope, activity, exposure(s), dose, contamination level(s), equipment malfunction, model, serial #, etc.
8. Transport vehicle description, if applicable
9. Media attention

NOTE: Personal or sensitive information, i.e., names, personal address, social security #, etc. should not be included in event descriptions.

d. NRC Operations Center

The NRC Operations Center staff will promptly notify the appropriate Region Duty Officer (RDO) of Agreement State events. No separate notification of the appropriate NRC Region by an Agreement State is necessary.

e. Event Notification System

All events reported to the NRC Operations Center will be entered into the Event Notification (EN) database. The EN will be publicly available through Internet on NRC's external home page at (http://www.nrc.gov/opa) under "Event Reports," within one day or less of notification. As a result of public access to this information, Agreement States may receive contacts from the public or media requesting additional information.

f. Preliminary Notifications (PN)

Agreement States should be aware that the NRC regional staff may prepare Preliminary Notifications (PN), which are brief summary reports of significant events, as appropriate, based on information provided by the Agreement State. Region staff may contact the State for additional information on the event. PNs

are usually issued within approximately two hours of notification of the occurrence of a significant event. The PN will be publicly available through Internet on NRC's external home page under PN Reports at (http//www.nrc.gov/opa). Updates to PNs occur when significant additional information about an event is provided to NRC.

g. NMED Initial Data Entry Record and NMED Follow-up Reports for "Significant" Events

Information about "significant" events initially reported to the NRC Operations Center will be entered into NMED by the NRC. The Agreement State initially reporting the event is responsible for updating the initial NMED report with revised or new information. In most cases this can be accomplished by reviewing the licensees written event report and updating the initial event information incorporated into NMED by one of the reporting methods described in Section 1.3 or 1.4. The NMED event report update should be submitted within 30 days of receipt of the licensee's written report by the Agreement State. If the licensee submits multiple written reports, more than one NMED event report update may be required for all new or revised information.

h. NRC Review of Significant Material Events

Both NRC and Agreement State events identified as having a "significant" potential risk to public health and safety will receive appropriate NRC management review. This review may be related to the reporting of additional information to the NMED database or may become part of a separate NRC initiative. Based on the "significance" of the event and/or the possibility of generic issues, the NRC may request that the State provide a final report. Additionally, based on the "significance" and/or generic implications, NRC staff may review and follow-up through closure (complete and final information has been received from the licensee; and the NRC or Agreement State evaluation is complete). The State may be requested to participate in NRC management briefings by telephone to keep NRC informed of actions taken by the State and others to protect public health and safety.

1.3 Electronic Reporting to NMED via PC Diskette or E-mail: Routine Event Reports and Follow-up Information on Routine and Significant Events (routine = 5-day Event Report, 15-day Medical Misadministration Report; 30 and 60 day Event Reports)

a. Routine NMED Event Reports

1. The Agreement State should provide an electronic NMED report via E-mail or PC diskette to NRC based on the information provided by the

Agreement State licensee in the 5, 15, 30 or 60 day report. (for reference, NRC routine reporting requirements are presented in Tables 1.1 and 1.2 on pages 7 through 10.)

2. The Agreement States assigned event report identification number (State\Yr.\No., e.g., GA-97-001) should be included in the NMED record. This will ensure that all information on a given event is contained in one record, eliminate duplicates, and aid in searching for information on events that have occurred in a specific State. The NMED record should be updated as new or clarifying information is developed. Follow procedures for data entry contained in the NMED Coding Manual provided by INEEL.

b. NMED Event Report Updates (follow-up information on both significant and routine events)

1. The initial event report identification number (State\Yr.\No.) should be included whenever additional follow-up event information is provided to NRC. Indicate that it is a follow-up report.

2. Any follow-up information that revises earlier information or provides additional information on a given event should be provided to NRC to ensure a complete historical NMED record. Follow-up information necessitating an NMED event update may be found in licensee event reports, results of any evaluations or investigations, dose assessments, leak tests, inspection reports, corrective actions, etc. Information on sealed sources and devices should include the manufacturer, model No. and serial No., and identify whether or not the lost or stolen gauge or material has been found. The follow-up event information may be provided in writing or extracted, summarized, and entered into NMED. Follow the procedures for filing NMED event update reports in the NMED Coding Manual provided by INEEL. Follow guidance below in item 1.4 for non-electronic (written) event reports.

3. Additionally, when providing follow-up NMED event information, provide clear reference to documents on file that the State used to generate the NMED event reports, e.g., licensee inspection report dated mm/dd/yr., if applicable and appropriate.

1.4 Non-Electronic Reporting of Material Events (Written Reports): Routine Event Reports and Follow-up Information on Routine and Significant Events

(Routine: 5-day Event Report, 15-day Medical Misadministration Report, 30 and 60 day Event Reports)

The following guidance is provided for Agreement States that report event information through submission of written reports. NOTE: Initial reporting of "significant" events should always be reported via telephone or FAX to the NRC Operations Center within 24 hours of notification by an Agreement State licensee (see Section 1.2).

a. **Event Report Cover Page:** An Event Report Cover is included on page 18 of this Handbook. The Event Report Cover page should be included as the cover page for all written Agreement State licensee event information provided to NRC. The cover page will ensure proper identification and coding as an Agreement State Event Report.

b. **Event Report Number:** Include the assigned event report number [Agreement State Identification No., (e.g.CO-98-001)] where indicated, on the cover page to avoid duplication of effort.

c. Written event reports should be sent to the Director, OSP.

d. Written report information should be comparable with the level of detail on an event that is specified in the "NMED" database and applicable regulatory requirements. A State may print out the NMED screens or provide a copy of the licensees event report to NRC. A listing of the minimum basic information to be provided on a given event that is necessary for the NMED database is provided in item 1.14, page 19. A listing of the basic information for preparing a medical event report is also provided (see item 1.15, page 20).

e. All follow-up information that revises the initial event information or provides additional information should be provided through close-out of the case. Send written event report information, along with a cover page (see p. 18 of the Handbook) to the Director, OSP.

1.5 Public Availability of Event Information

Any event information that is considered preliminary predecisional information by the State should be clearly identified on the cover page as follows: **"Preliminary, Not for Public Disclosure."** For event information in NRC's possession, the final determination on whether to withhold from public disclosure will be made by NRC on a case-by-case basis in accordance with the requirements of 10 CFR Part 9.

TABLES:

The following four tables are provided. NRC 10 CFR reporting requirements are contained throughout the 10 CFR rather than contained in one Part or Section. Therefore, the following tables provide a complete listing of the current 10 CFR material reporting requirements in one place. Additionally, the tables further differentiate significant and routine reporting requirements. The tables are listed as follows: 1.1 Event notification by category and NRC reporting requirement, 1.2 Event Reporting Requirements, 1.3 Examples of reportable events, and 1.4 Sample NMED data entry screens.

TABLE 1.1 EVENT NOTIFICATION BY CATEGORY AND NRC REPORTING REQUIREMENT

	SIGNIFICANT EVENTS (POSSIBLE AO)		ROUTINE EVENTS (POSSIBLE AO)	
REGULATORY REPORTING REQUIREMENT	IMMEDIATE NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 1 HR.	PROMPT NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 24 HRS.	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 30 DAY LICENSEE EVENT REPORT (LER)	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 60 DAY LER REPORT
10 CFR Part 20, Standards for Protection Against Radiation	§20.1906(d)(1) and (d) 2)			
	§20.2201(a)(1)(I)		§20.2201(a)(1)(I) and (ii)	
	§20.2202(a)	§20.2202(2)(b)		
			§20.2203(a)	
10 CFR Part 21, Reporting of Defects and Noncompliance[1]				§21.21(a)(1) and (2)
10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material	§30.50(a)	§30.50(b)	§30.50(a) and (b)	
10 CFR Part 31, General Domestic Licenses for Byproduct Material			§31.5(c)(5)	
10 CFR Part 34, Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations		§34.25(d) NOTE: 5 day report	§34.30(a)	

[1]Not a compatibility requirement for Agreement State, but States voluntarily provide information on equipment failure and defects.

Table 1.1 Event Notification cont.

SIGNIFICANT EVENTS (POSSIBLE AO)			ROUTINE EVENTS (POSSIBLE AO)	
REGULATORY REPORTING REQUIREMENT	IMMEDIATE NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 1 HR.	PROMPT NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 24 HRS.	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 30 DAY LICENSEE EVENT REPORT (LER)	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 60 DAY LER REPORT
10 CFR Part 35, Medical Use of Byproduct Material[2]		§35.33(a),(1),(2),(3) and (4)		
10 CFR Part 36, Licenses and Radiation Safety Requirements for Irradiators		§36.83(a) and (b)	§36.83(a) and (b)	
10 CFR Part 39, Licenses and Radiation Safety Requirements for Well Logging		§39.77(a),(b) and (c)	§39.77(b)	§39.77(a),(b),(c) and (d)
10 CFR Part 40, Domestic Licensing of Source Material		§40.60(a)	§40.60(b)	§40.60(c)(2)
10 CFR Part 70, Domestic Licensing of Special Nuclear Material		§70.50(a)	§70.50(b)	§70.50(c)
10 CFR Part 71, Packing and Transportation of Radioactive Material			§71.47,71.87 and 71.95	

[2]Misadministration event requires 15 day LER report and 24 hour notification to referring physician and patient.

Table 1.2 EVENT REPORTING REQUIREMENTS

Typical items covered under reporting requirements include the following:

10 CFR Part	Reporting Requirement	Notification
20.1906(d) (1)	reports of removable contamination on package > limits in 10 CFR 71.87.	Immediate
(d)(2)	radiation levels on package > limits in 10 CFR 71.47	Immediate
20.2201(a)(1)(i)	reports of theft or loss of licensed material ≥ 1000 X App C value	(i) (I) Immediate.
(a)(1)(ii)	reports of theft or loss of licensed material ≥ 10 X App. C value	(ii) 30 day
20.2202(a)(1)	exposure (real or threatened) ≥ TEDE of 25 rem (.25 Sv), or eye or lens dose equiv. of 75 rem (.75 Sv) or shallow dose equiv. (skin\extremities) of 250 rads (2.5 Gy).	(a)(1) Immediate
(b)(1)	exposure (real or threatened) ≥ TEDE of 5 rem (.05 Sv), or eye or lens dose equiv. of 15 rem (.15 Sv), or shallow dose equiv. (skin\extremities) of 50 rads (.5 Gy).	(b)(1) 24 hours
20.2202(a)(2)	release where individual could have intake > 5 X ALI over 24 hours.	(a)(1) Immediate
(b)(2)	release where individual could have intake > 1 X ALI over 24 hours	(b)(2) 24 hours
20.2203(a),(b)	radiation exposures, releases or concentrations of radioactive material that exceed the limits.	30 day
21.21(a)(1-2)	reporting of defect in basic component, structure or system.[3]	60 day
30.50	reporting of events involving:	
(a)	prevention of immediate protective action, involving exposures or releases that could exceed regulatory limits	4 hour
(b)(1)	unplanned contamination restricting access >24 hours (no isotopes with half-lives <24 hrs)	24 hour
(b)(2)	equipment failure or disability to function as designed when equipment is required to be available and operable and no redundant equipment is available and operable.	24 hour

[3]Not a compatibility requirement for Agreement States, but States voluntarily provide information on equipment failure and defects.

Table 1.2 Event Reporting Requirements cont.

10 CFR Part	Reporting Requirement	Notification
30.50 cont.		
(b)(3)	unplanned medical treatment of contaminated person,	24 hour
(b)(4)	Fire, explosion affecting integrity of material, device or container.	24 hour
31.5(C)(5)	failure or damage to shielding, on-off mechanism or indicator, or ≥ 0.005 microcuries (185 Bq) removable radioactive material for generally licensed device.	30 day
~~34.25(d)~~ 34.27(d)	reporting of leaking sources, leak test results ≥ 0.005 μCu (185 Bq)	5 day
~~34.30~~(a) 34.101(a)	radiography source disconnect, inability to retract source, or component failure (critical to safe operation of device)	30 day.
35.33(a)	notifications and reports of misadministrations.[4]	Next day(24 hr)
36.83	irradiator events, release of material, defective components, systems or structures; (if not reported under other 10 CFR reporting requirements)	24 hour
34.35(d)(2)	reports of leaking sealed sources found during periodic leak testing requirements	5 day
39.77(a,c)	well logging source rupture, irretrievable source, abandonment	(a)Immediate (c) When apparent recovery impossible
40.60	requirements for domestic licensing of source material to receive, possess, use transfer, or deliver source and byproduct material. (NOTE: Same as 30.50 above)	
70.50	events involving special nuclear material (SNM)	
(a)		(a) 24 hour
(b)		(b) 30 day
(c)		(c) 60 day
71.47, 71.87	transportation events involving defective packaging of material, contamination	30 day

[4]Misadministration events require 15 day LER report and 24 hour notification to referring physician and patient.

TABLE 1.3 EXAMPLES OF REPORTABLE EVENTS

This Table provides examples of reportable material events or occurrences that are required to be reported by both NRC and Agreement State material licensees. The Table addresses specific reporting requirements for either immediate notification (within 24 hours or less) or 30 day written reports. The Agreement States should provide detailed event information that is comparable with the NMED database system.

Immediately reportable under 10 CFR 20.2201	**Stolen Portable Gauge** Licensee reported that a [Manufacturer] [Model #] [serial #] portable gauge containing 9 millicuries of cesium-137 and 40 millicuries of americium-241:beryllium was stolen from the licensee's vehicle parked at the licensee's facility. The gauge was padlocked in its original carrying case. The State is following the incident and working with local authorities to develop a press release. Follow-up information will be provided to NRC on the recovery of the stolen gauge and entered into NMED.
Reportable within 24 hours under 10 CFR 30.50	**Possible Damage to Portable Gauge** Licensee reported that a [Manuf.] [Model #] [serial #] portable gauge was run over by a bulldozer at a field construction site. The gauge housing appeared to have been damaged, but the source appeared to be intact. The licensee is investigating why the radiographer failed to maintain constant surveillance. The gauge will be sent to the manufacturer for leak testing. A follow-up report will be provided to the State by the licensee, and the State will share information on the results of the licensees investigation into the occurrence and the results of the leak test with NRC through entry into NMED.
Reportable within 30 days under 10 CFR 71.47 and 20.1906	**Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits** A medical licensee reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages with an ion chamber detector found radiation levels of 250 millirem per hour on one package, which exceeds the state and federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultants review of the event, and the information will be entered into NMED.
Reportable within 24 hours under 10 CFR 20.1301, 20.2203	**Exposure to Nonradiation Worker at a Licensed Facility** A licensee reported to the State that a nonradiation worker had received an exposure as a result of picking up a 5 curie Americium-241:Beryllium neutron source used for well logging and placed it in his pocket. The worker, a temporary contractor employee, was cleaning a well logging tool at the licensee facility. (The licensee was under the assumption that all of the source material had been removed from the equipment.) While cleaning the tool, the source fell out, and the worker picked it up and placed it his pocket. The worker was not a radiation worker and had no knowledge of what the object was. Preliminary calculations performed by [identify Consultant/Contractor] indicate that the individual may have received a dose of 4-6 Rem. The licensee's RSO is investigating the incident. The State plans to keep NRC informed of the ongoing results of the investigation, and the information will be entered into NMED.

Reportable within 24 hours under 10 CFR Part 35 and 30.50(b)(2)	**Possible Misadministration involving a Teletherapy Unit Malfunction** A patient undergoing a Cobalt-60 teletherapy treatment with a [Manufacturer][Model #] received an unintended exposure. The RSO estimated that the patient received an exposure of 138 centiGray (Rads) to a depth of 0.5 centimeters to the wrong treatment site, based on a possible total treatment time of 1.5 minutes. The exposure occurred as a result of two power disruptions during a thunderstorm. The loss of electrical power caused the unit table to move which resulted in treatment to the wrong site. The patient received 0.35 minutes of the intended fractionated treatment time of 1.5 minutes. The patent was prescribed a total dose of 5040cGy to be given in 28 fractions of 180 cGy per day at the rate of 5 fractions per week. The prescribing physician elected not to make up the missed dose. The prescribing physician indicated that the patient is not expected to have any adverse effects from the misadministration. The patient and referring physician were notified of the event. The licensee was able to recreate the event to demonstrate how the event occurred. The licensee has contacted the manufacturer. The State will keep NRC informed of the results of the review for any generic implications.
Reportable within 24 hours under 10 CFR 36.83(9)	**Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility** Licensee notified the State that the controls at a Co-60 irradiator facility were indicating that the water level was low, circulating pump off, and fill valves were open. The pool water level gauge indicated a pool water level of 93 inches, well below the normal level of 137 inches. Previous incidents indicated that a loss of compressed air pressure to the water level gauge could result in an erroneously low water level gauge reading, causing the automatic pool fill valves to open, and the pool water circulating pump to turn off. The compressed air system pressure was found to be in the normal range, but the operator found water and congealed oil in the air line supplying the pool water level gauge, and the air line supplying the elevator control valve. Further investigation found that the compressed air line water traps were full of water. A past similar incident resulted in a failure to raise the elevator. The operator then verified that the pool water level was in fact normal. The licensee requested the building maintenance personnel to diagnose and repair the compressed air supply immediately, to prevent the conductivity in the pool water from reaching abnormal levels as a result of the resin filter circulating pump being automatically turned off by the false low pool water level meter reading. Maintenance personnel responded and replaced a failed compressed air dryer, and monitored the open air lines to clear the lines of water. A float activated automatic water drain was installed in the air line to prevent a possible reoccurrence by allowing any water to automatically drain from the air line.

1.6 Nuclear Material Events Database (NMED) Sample Data Entry Screens

The following pages contain sample data entry screens from the NMED database which shows the level of detail the States need to provide for a given event. Detailed NMED user information is contained in the NMED Coding Manual provided by INEEL along with the software to the Agreement States.

"This information request has been approved by OMB 3130-0178, expiration date 06/30/2000. The estimated burden per response to comply with this collection request is 1.25 hours. Forward any comments regarding the burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0052), Office of Management and Budget, Washington, DC 20503. If a document does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB clearance number."

Table 1.4 Sample NMED Data Entry Screens (OMB 3130-0178).

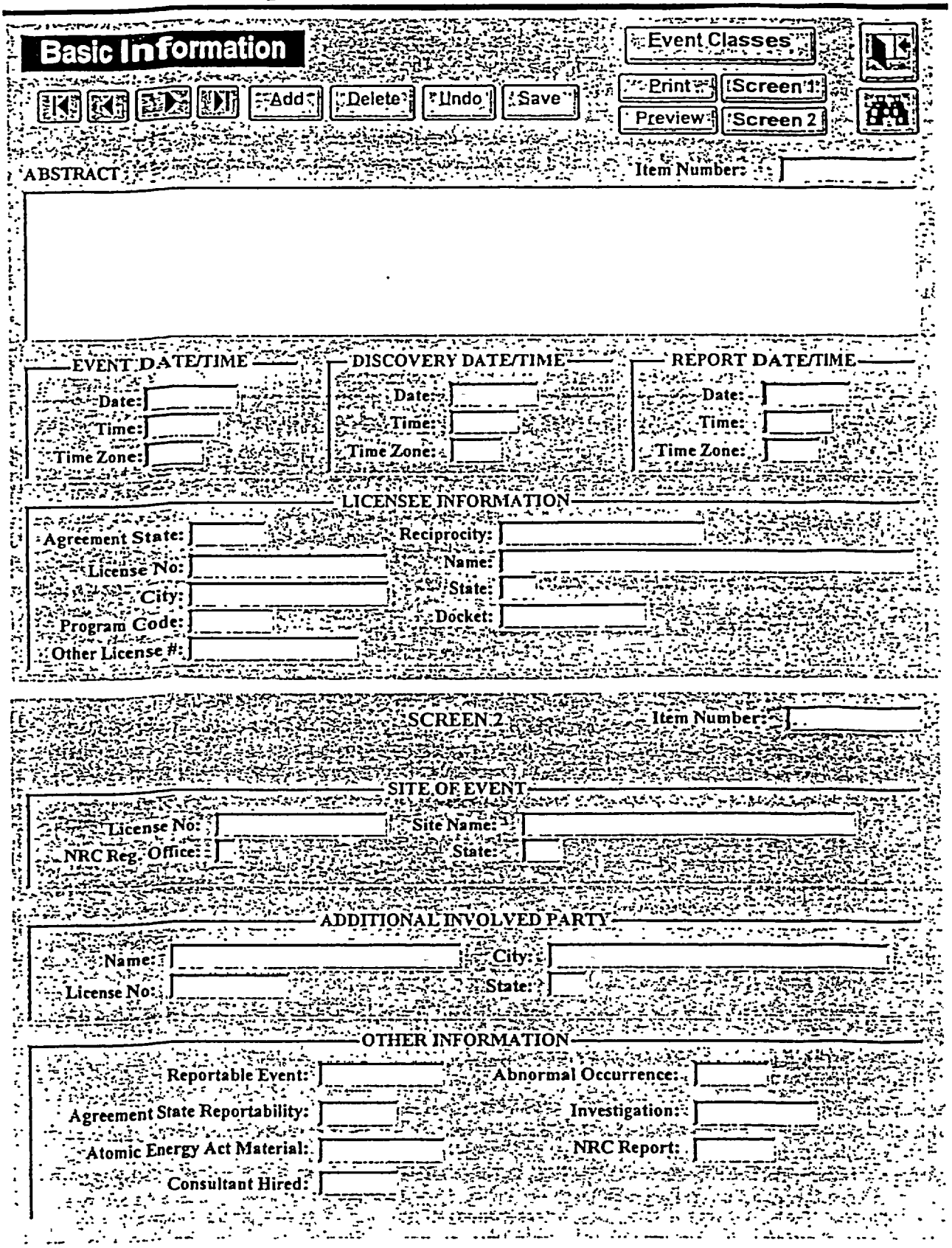
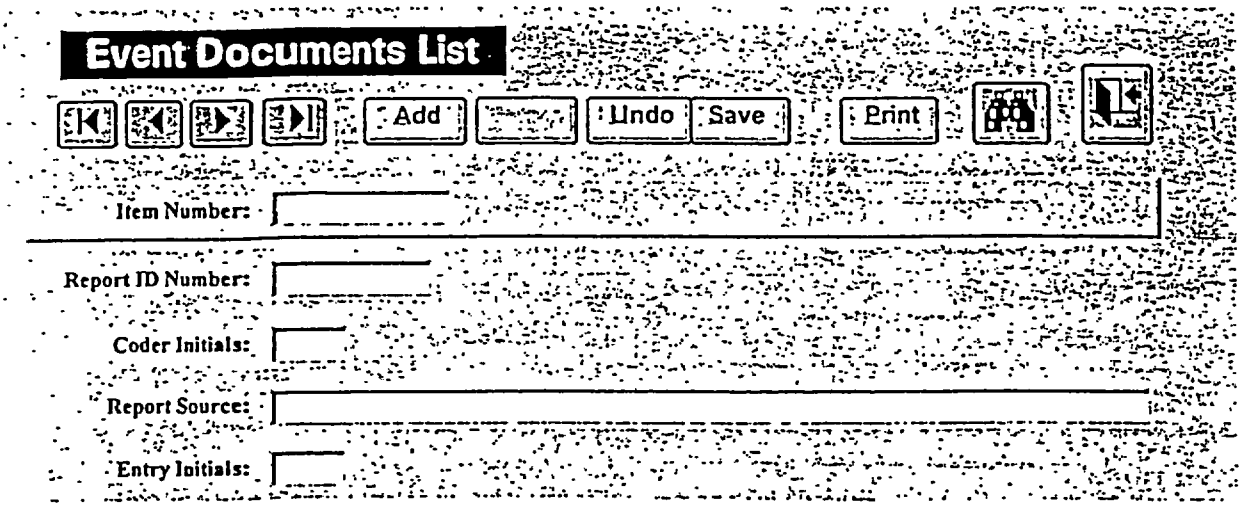
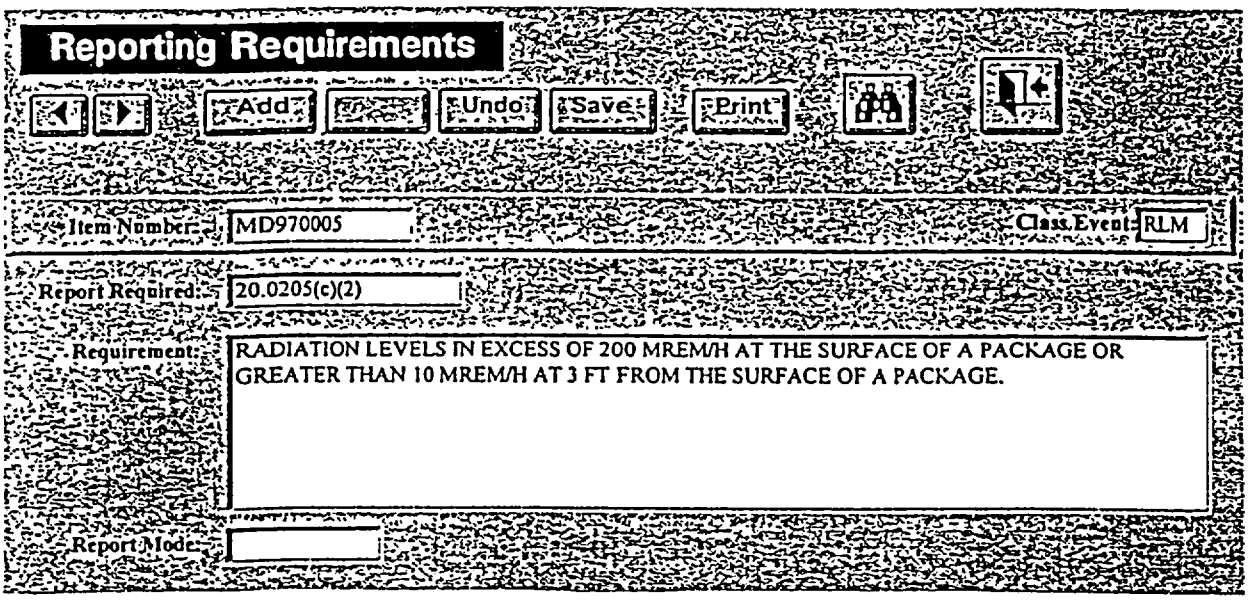


Table 1.4 NMED cont.





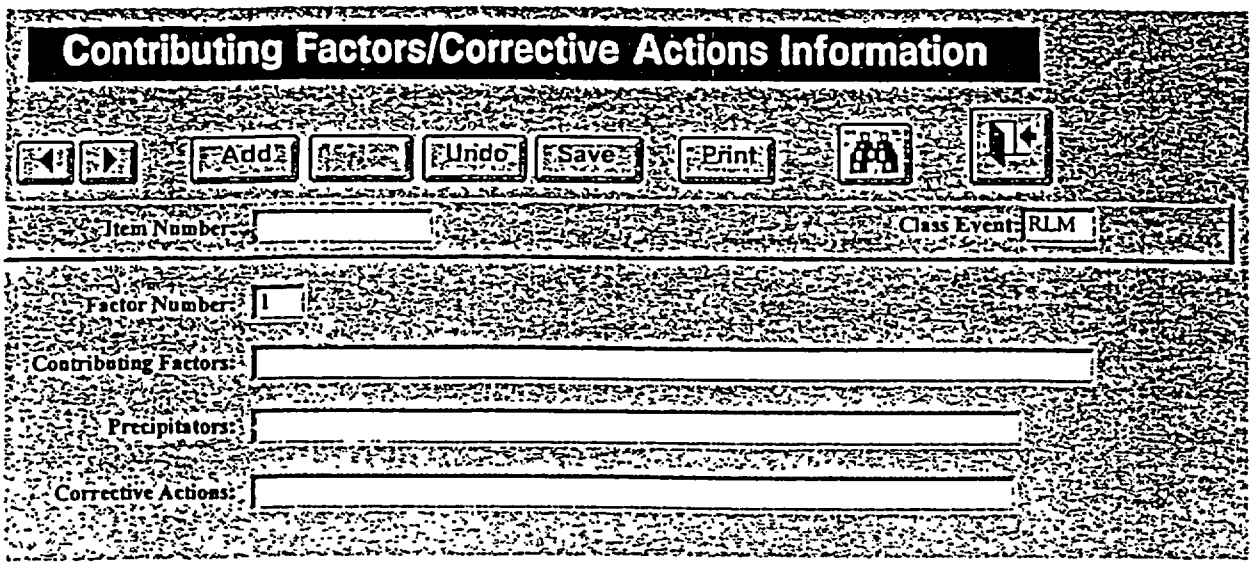
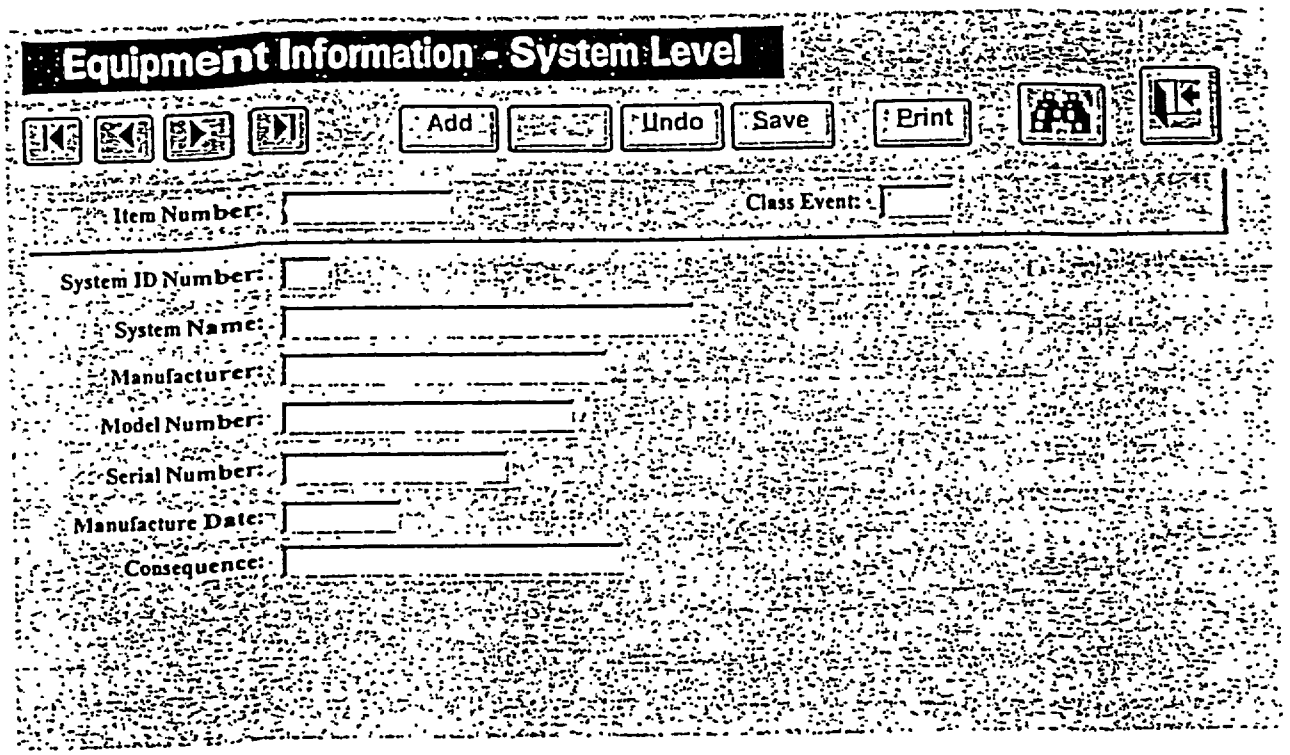


Table 1.4 NMED cont.



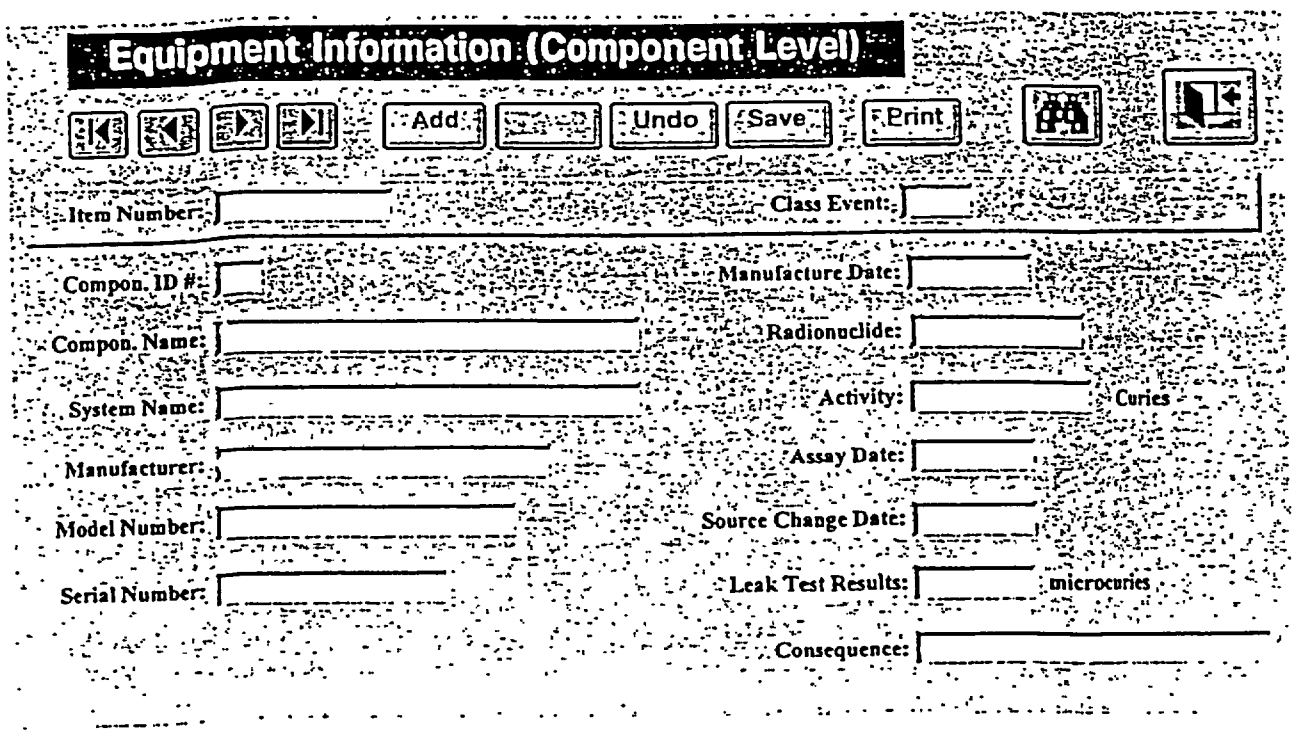


Table 1.4 NMED cont.

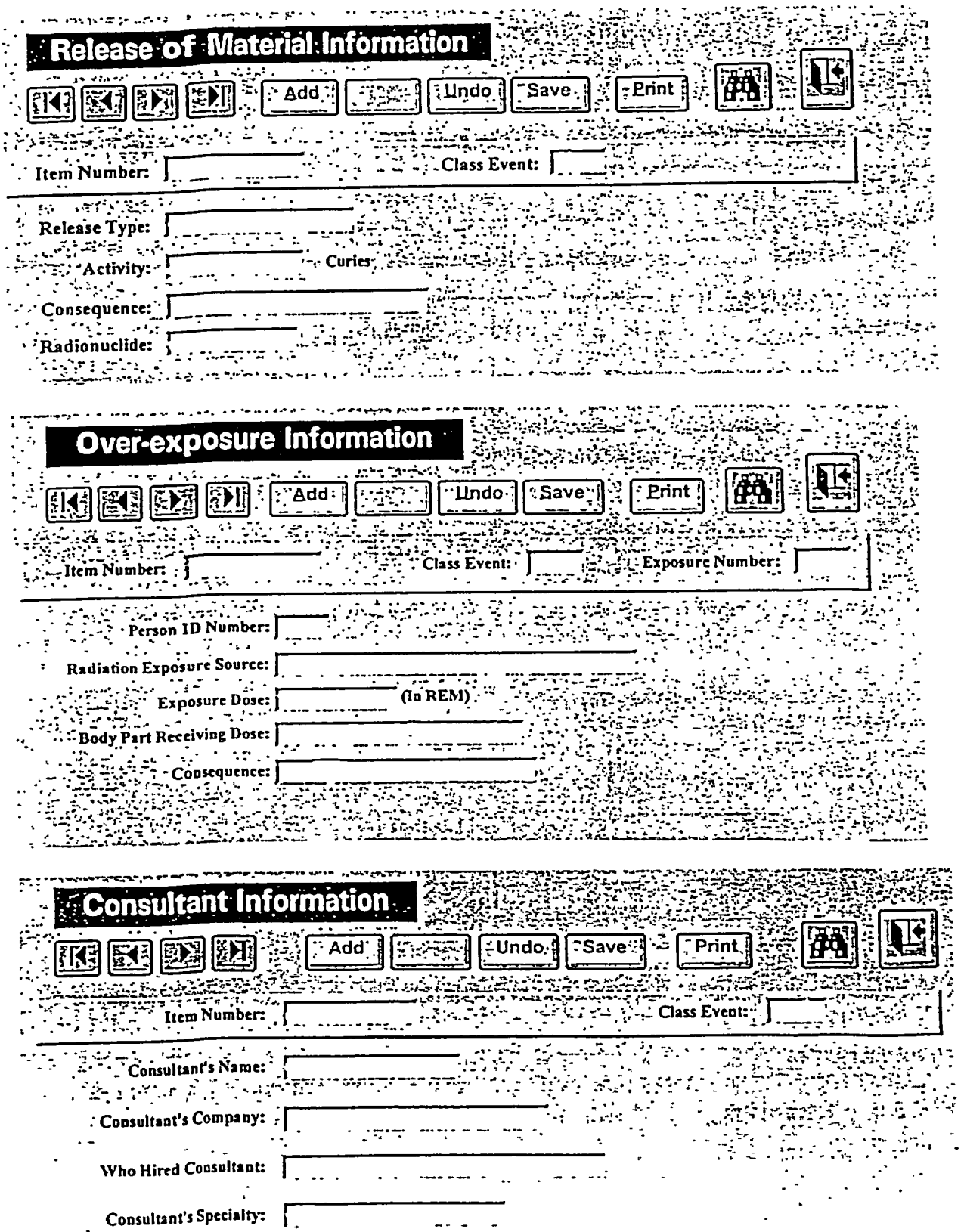
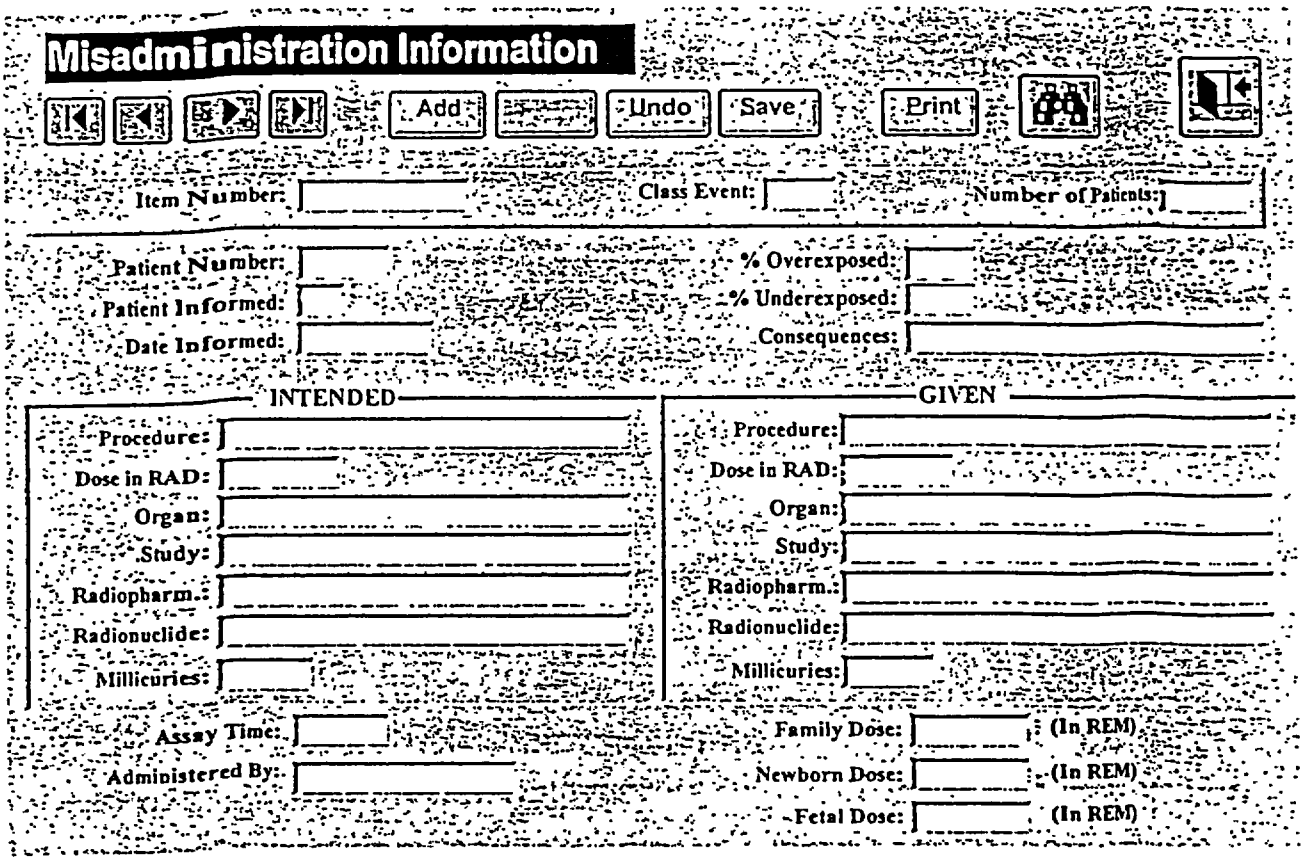
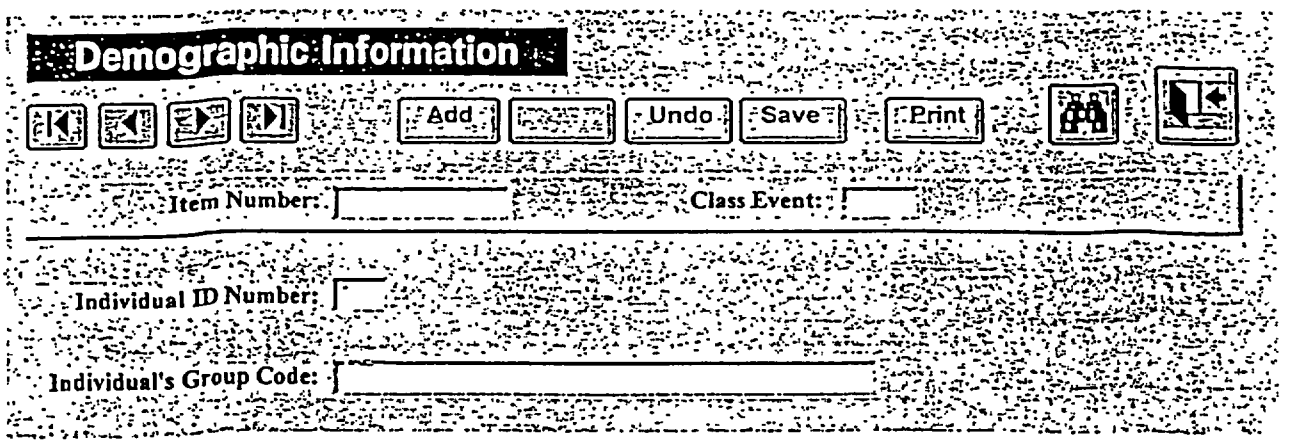


Table 1.4 NMED cont.





The following pages contain items 1.7 Sample Event Report Cover Page (for event reports provided in writing), 1.8 a listing of the basic information to be included in a written event report, and item 1.9 a listing of the basic information to be included in a written medical misadministration event report.

EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT ID NO. __ - __ - ___
(State\Yr.\No.)

DATE:

TO:
Director
Office of State Programs

SUBJECT:

STATE:

Signature and Title: _____

_____

_____

_____

1.8 EVENT REPORT (Basic Information)

This list is an option for those Agreement States who choose not to enter event data electronically into the Nuclear Material Events Database (NMED). The information provided must be compatible to the information needed for the NMED system and presented clearly in readable form.

(a) Licensee (Name, city and State)

(b) Agreement State ID No. (NY-97-001) (MS-97-001), State ID, year, sequentially assigned ID number.

(c) Type of License

(d) License No.

(e) This Item No. (Follow-up Report No. 01, 02, etc.)

(f) Abnormal Occurrence (Y\N). See AO Criteria contained in NUREG-0090

(g) Isotope (i.e., Cs-137; Ir-192, Co-60, Am-241, Po-210 etc.
- Activity
- Need to clearly show radiopharmaceuticals, as well as isotopes.

(h) Type of Isotope and activity (AEA material, accelerator produced, NORM)

(I) Date of Event

(j) Date of this Report

(k) Amount of Radioactive Material

(l) Events Involving Overexposure
- No. of Individuals Overexposed
- Source of Radiation
- Type of Individual (occupational worker, member of the public)
- Event Location
- Dose Estimated to Individuals Involved in the Event (In REM)
- Body Part Receiving Dose
- Consequence

(m) Leaking Source
- Leak test information

(n) Lost or Stolen Material

1. Nuclear Material
- Event
- Event Location
- Probable Disposition

2. Sealed Sources and Devices
- Type
- Manufacturer, Model No.
- Serial No.
- Disposition/Recovery

(o) Release of Material
- Form
- Event
- Location
- Activity (Curies)

(p) Events Involving Radiography
- Location
- Equipment description Manufacturer, Model No.
- Event

(q) Event Involving an Irradiator

(r) Events Involving Teletherapy

(s) Transportation Event
- Location
- Shippers name and address
- Package type
- Package Identification No.

(t) Regulatory reporting requirement (Indicate applicable licensee reporting requirement)

(u) Demographic information

(v) ABSTRACT: Include where, when, how, and why. (Describe the cause of the event(s), contributing factors, persons involved, consequences, and licensee corrective actions taken or planned.) Attach a copy of the licensee's 30 day report, where applicable.

1.9 MEDICAL MISADMINISTRATION (Basic Information)

This list is an option for Agreement States that choose not to enter event data electronically into the Nuclear Material Events Database (NMED). The information provided must be compatible with information needed for the NMED system and presented clearly in readable form.

(a) Licensee (Name, City and State)

(b) Agreement State ID No. (NYC-97-001) (MS-97-001), State ID, year, sequentially assigned ID number.

(c) Type of License (Broad scope, private practice medical, etc.)

(d) License No.

(e) This Item No. (Follow-up Report No. 01, 02, 03, etc.)

(f) Abnormal Occurrence (Y/N). See AO Criteria contained in NUREG-0090.

(g) Patient\Responsible Relative Notified (Y\N)

(h) 15 day Written Report Provided (Y\N)

(I) Date of Event

(j) Date of this Report

(k) Regulatory reporting requirement (Indicate applicable licensee reporting requirement)

(l) ABSTRACT:
Initial report: Include where, when, how, cause, provide as much information as is known at the time of the initial report).

Procedure/Study: Actual and intended

NOTE: Need to clearly show radiopharmaceuticals, as well as isotopes.

Isotope and dose involved: (i.e., 200 μCi of Iodine Hippurate I-131; 5 mCi of Iodine-125; 10 mCi of Iodine-131; 40 mCi of Cs-137; 2 mCi of Tc-99m; 5 mCi of P-32, etc. (clearly identify chemical and physical form).

Exposure: Intended and actual

Treatment plan: fractionations, if any.

Device (Equipment) involved: High Dose Rate Afterloader, Make and Model No. ____ (where applicable).

Systems: Computer program and developer, where applicable.

Referring Physician notified: (Y\N)

Patient notified: (Y/N)

Include information on all person(s) that may have been involved including employees, i.e. assistants, technicians, nurses, etc. Where applicable, describe the prescribed treatment plan and the actual treatments administered, including fractionations, include consequences. Provide an assessment of any expected effects on all those who were exposed, for unusual cases it may be necessary to include a medical consultant. Consultant used, identify. Describe licensees corrective actions.

Updated Information: provide any updated information in future reports, use the Original Item ID# (MS-97-001) and indicate on the cover page that it is updated information.

Demographic information (Description)

SECTION II

Abnormal Occurrence Guidelines and Criteria

2.0 ABNORMAL OCCURRENCE GUIDELINES AND CRITERIA

2.1 Introduction

This section presents the guidelines and criteria to be followed when assessing the significance of an event or occurrence to see if it meets the criteria established to identify an abnormal occurrence. Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438, 42 USC 5848) identified an abnormal occurrence (AO) as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health and safety. Section 208 of the Act also requires that the Commission inform Congress of any abnormal occurrences. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect public health and safety by providing information on proposed abnormal occurrences that have occurred in their State.

2.2 Abnormal Occurrence Policy Information

The Commission submits a report to Congress identifying any abnormal occurrences. The Federal Reports Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis (see "Report to Congress on Abnormal Occurrences, Fiscal Year 1996," NUREG-0090, Vol. 19). Section 208 of the Act indicates that each report shall contain:

(1) The date and place of each occurrence;
(2) The nature and probable consequence of each occurrence;
(3) The cause or causes of each; and
(4) Any action taken to prevent recurrence.

As specified in Section 208, within 15 days of receiving information of each AO, the Commission shall provide as wide dissemination to the public as reasonably possible as soon as such information becomes available.

A final AO policy statement containing criteria for determining an AO was published in the *Federal Register* on December 19, 1996, (61 FR 67072). Revised AO criteria were published in the *Federal Register* on April 17, 1997 (62 FR 18820) to incorporate minor changes and to revise criterion III covering Fuel Cycle Licensees.

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. This type of incident or event would have a

moderate or severe impact on the public health or safety and could include, but need not be limited to the following:

(1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
(2) Major degradation of essential safety-related equipment; or
(3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

2.3 Agreement State Proposed AOs

Agreement State staff should screen events against the AO criteria and identify potential AO events as part their routine program to inform NRC of all events reported by Agreement licensees. In addition to routine reporting of significant and routine events to NRC, Agreement States are requested to prepare a special written report for potential abnormal occurrences. Agreement State staff should follow the guidelines for preparing AO write-ups contained in Section 2.5 of this "Handbook." When questions arise on a given event, it may sometimes be necessary for NRC to directly contact an Agreement State representative and request additional information.

2.4 Abnormal Occurrence Criteria (Appendix A, 62 FR 18822)

Criteria by types of events used to determine which incidents or events will be considered for reporting as AOs are as follows:

I. For All Licensees.

A. Human Exposure to Radiation from Licensed Material.

1. Any unintended radiation exposure[5] to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement.

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has

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An "unintended radiation exposure" includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in §35.2) involving the wrong individual that exceeds the reporting values established in the regulations.

All other reported medical misadministrations will be considered for reporting as an AO under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.

demonstrated compliance with §20.1301 using §§20.1302(b)(1) or 20.1302(b)(2)(ii).

- *Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material; (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).*

C. *Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.*[6]

1. *Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.*

2. *A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.*

3. *Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.*

Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

4. *Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.*

D. *Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials).*

1. *An accidental criticality [10 CFR 70.52(a)].*

2. *A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.*

3. *A serious deficiency in management or procedural controls in major areas.*

4. *Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.*

II. *For Commercial Nuclear Power Plant Licensees.*

A. *Malfunction of Facility, Structures, or Equipment.*

. *Exceeding a safety limit of license technical specification (TS) [§50.36(c)].*

2. *Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.*

3. *Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).*

B. *Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy.*

. *Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.*

. *Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could*

occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

III. For Fuel Cycle Facilities.

1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.

2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

IV. For Medical Licensees.

A medical misadministration that:

(a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and

(b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (I) is the wrong radiopharmaceutical,[7] or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

Guidelines for "Other Events of Interest."

The Commission may determine that events other than AOs may be of interest to Congress and the public and be included in an Appendix to the AO report as "Other Events of Interest." Guidelines for events to be included in the AO report for this purpose are items that may possibly be perceived by the public to be of health or safety significance. Such items would not involve a major reduction in the level of protection provided for public health or safety; therefore, they would not be reported as abnormal occurrences. An example is an event where upon final evaluation by an NRC Incident Investigation Team, or an Agreement State equivalent response, a determination is made that the event does not meet the criteria for an abnormal occurrence.

The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

2.5 GUIDELINES FOR ABNORMAL OCCURRENCE WRITE-UPS

All AO write-ups should be complete, up-to-date, and written using text that is understandable to non-technical readers. Please do not use bold or italics in writeups; use underline instead. Any special fonts will be added during the publishing stage by the Technical Publications Specialist using the Kodak Ektaprint Electronic Publishing System.

NOTE: Those Agreement States that already have INTERNET E-Mail capability may electronically send their AO information to OSP via Internet using WordPerfect or an ASCII text file. NRC is currently using WordPerfect 6.1. The file may be attached to an e-mail transmission. The OSP AO coordinator, Patricia Larkins, may be reached at (PML@NRC.GOV).

Margin notation - Indicate the Original ID No., State ID-YR..-ITEM NO. (XX-94-01).

First paragraph - State the AO criteria for the event by citing the appropriate section of the AO criteria.

Date and Place - Provide the date the event occurred, the licensees name, and the city and state address of the licensee.

Nature and Probable Consequences - Briefly explain what happened and what were the circumstances. Provide the specific details of the event, i.e., exposure (where applicable), source, indicate the specific isotope(s), quantity, dose (where applicable), treatment plan (where applicable), equipment, manufacturer and Model No. Describe any immediate actions taken by the licensee or the State (confirmatory action letter, special inspection, enforcement conference, enforcement action(s), etc.). The write-up should answer where, when, how, why, and efforts to prevent recurrence.

For occupational, medical, or public overexposures identify whether the person was notified. For medical misadministrations, include the intended and actual treatment plan, identify any health effects. Mention if a medical consultant has been contracted to review the event. Include the consultant's conclusions and identify the effects on the patient. Never mention any health effects on a patient without attributing the statement to the licensee or medical consultant. Indicate whether the primary physician was notified.

NRC policy states that all documents must be published in dual units (Metric and English).

Cause or Causes - Self explanatory

Action(s) taken to prevent recurrence - Briefly explain what actions were taken to prevent recurrence by the licensee, and indicate whether or not the State directed the licensee to take the specific action(s), i.e., was State satisfied with the licensee's corrective actions, if so, please indicate that the "state was satisfied with the following corrective actions taken by the licensee ...." or "the licensee has complied with the corrective actions recommended by the State as follows . . " Were there any enforcement actions, penalties, etc.?

Last paragraph - Indicate the status by stating whether the AO is closed or remains open waiting for additional significant information from the Agreement State licensee. An item should only be identified as open if the State expects additional significant action may take place that will be covered in a follow-up report. The new information contained in the follow-up report should be provided to NRC for inclusion in the AO report under the section entitled "Update to Previously Reported AOs."

The following pages contain two sample AO write-ups.

Fig. 2.1 SAMPLE INDUSTRIAL RADIOGRAPHY AO REPORT

State ID-Yr.-No.
(XX-97-01)

Industrial radiography overexposure at (Name of facility, City, State) location.

In accordance with the AO criteria an annual shallow-dose equivalent to the skin or extremities greater than 2500 mSv (250 rem) is considered an abnormal occurrence.

Date and Place: The Agency was notified on (notification date), by (Licensee), that a radiography overexposure had occurred on (event date), at (facility, location (Catastate)).

Nature and Probable Consequences: On (event date), at approximately 7:00 PM, a radiography trainer working for (Licensee) in (facility, location, (City, State)), experienced a source disconnect of a 96 curie iridium-192 radiography source, that resulted in an extremity exposure of at least 500 rem to the thumb and index finger of a radiographer's left hand. The radiography trainer was radiographing welds on a 12 inch pipe line in a five foot deep ditch at (Licensee), and began experiencing difficulty with the source exiting from and retracting into the camera earlier in the day. After completing a radiograph, while trying to retract the source to the shielded position, survey meter readings indicated a source disconnect. The radiographer got a one inch thick lead sheet from the radiography truck and covered the source in the guide tube. By this time it was dark. The radiographer helper rope off a larger area and stayed a distance from the source. He then asked the (Licensee) inspector to notify the radiography company RSO, but to tell him that everything was under control, and that the radiographer could handle the situation. As the trainer disconnected the guide tube, the source assembly fell into the mud at the bottom of a ditch. While picking up the source assembly from the mud with channel lock pliers, the source slipped. He instinctively reached for and straightened the source assembly (pigtail) with his hand, apparently touching the source in the process. He placed the pigtail into the camera, intending to place the source capsule in first. He noticed the survey meter reading high, indicating the source was outside of the camera. The radiographer then removed the source from the camera and placed it under the lead sheet. He then removed the lockbox from the camera, inserted the

Source\Quantity

Exposure

NOTE: Emphasis added [bold] to clarify specific information that should be included in the report

sheet. He then removed the lockbox from the camera, inserted the source end of the pigtail, replaced the lockbox and locked it. The source was now secured in the shielded position. The barricades were taken down, the equipment was loaded on the truck, and the crew returned to the office. The company did not notify the Agency of the disconnect.

About 10 days later, the radiographer started experiencing discomfort in his left thumb and index finger and visited a doctor for treatment on March 9, 1994, March 14, and April 1, 1994. On April 11, 1994, the RSO and the radiographer visited the Agency office and reported the incident. The Agency investigated the incident at this time. The radiographer's film badge reading was 1.06 rem whole body. An inspection of the camera was performed by the company RSO the day after the incident. The Licensee and the State Agency determined that the company had ordered two model #22 pigtails and sources from (Manufacturer, City, State), for the company's Gamma Century radiography cameras. (Manufacturer) inadvertently sent a model #22 and a Model #23 pigtail instead of the two model #22's ordered. The two models appear similar, but close examination reveal two differences. The model #22 is manufactured with 1/8 inch aircraft cable and a 3/4 inch connector, the model #23 is manufactured with teleflex cable, the same as the drive cable material, and a one inch connector. The model #23 is not made to be used in the Gamma century camera. The radiography company assumed the two pigtails sent to them were model #22's. The #23 was mistakenly placed in the Gamma century camera and is apparently the cause of the disconnect. The Agency investigation determined that the trainer had received at least a 1500 rem exposure to the thumb and index finger of the left hand. The (State) Radiation Control Program, in which the manufacturer was licensed, was informed of the incident and investigated the manufacturer's (Licensee) error in sending the two different pigtails to the radiography company.

Equipment\Device (Manuf.\Model No.)

Cause or Causes - The manufacturer's mistaken delivery of a pigtail model number different than the one ordered and the radiography company's assumption that the pigtails they received were the models they ordered, resulted in a pigtail being used in a camera for which it was not manufactured. The disconnect resulted from the difference in the length of the connectors between the two models. Also, the radiographer attempted an unauthorized recovery of the disconnected source. The radiographer was not trained in source recovery and had no previous experience with source disconnects.

Actions Taken to Prevent Recurrence

Licensee - Actions will be given at the enforcement conference.

Sate Agency - The Licensee and radiographer were cited for violations of the (State) Regulations for Control of Radiation. The Licensee was cited for the extremity exposure, unauthorized retrieval of a disconnected source, failure to immediately notify the Agency of the incident, and failure to notify the Agency in writing within thirty days of the incident. The radiographer was cited for unauthorized retrieval of a disconnected source. The incident has been referred for escalated enforcement.

Status

This file is (open\closed) in (State). The event will remain open for additional information from the State of (State).

Fig. 2.2 SAMPLE MEDICAL AO REPORT

State ID-YR.-NO.
(XX-9702)

Medical Brachytherapy Misadministration at
(Name of facility, City, State) location.

Criteria

In accordance with the AO criteria, administering a therapeutic dose that is at least 50 percent greater then the prescribed dose should be considered an abnormal occurrence.

Date and Place - The Agency was notified on **(Date)**, that a brachytherapy overexposure had occurred on **(Event** date(s)); at **Facility; City and State** location).

Procedure
Source(s)
Treatment plan
Device\Equipment

Nature and Probable Consequences - A 68-year-old woman with Stage II vaginal cancer was referred to the hospital's radiation therapy department for a gynecological brachytherapy procedure involving the afterloading of cesium-137 and iridium-192 sources. A plan was developed to deliver a total dose of 6000 centiGray (cGy) (6000 rad) by a combination of 4000 cGy (4000 rad) from an external beam (linear accelerator) and 2000 cGy (2000 rad) from vaginal implant therapy. The external beam therapy was completed on September 9, 1993. The patient was then evaluated and plans were made to complete the implantation portion of the treatment. The treatment plan for the implant therapy included calculations for the time required to deliver 6000 cGy (6000 rad). The dose already delivered by the external beam was not considered in the plan.

Actual vs. intended administration

The attending physician reviewed the dose calculations on October 9, the fourth day of the implant, and determined that the duration of the implant treatment was likely to have been too long. He immediately removed the implants. Calculations revealed that the patient received 4000 to 4500 cGy (4000 to 4500 rad) from the brachytherapy treatment. Two days later, on Monday October 11, the attending physician verified with the physics staff that his dose calculations were correct. The patient received a total dose of 8000-8500 cGy (8000-8500 rad), (4000 from external beam and (4000-4500 from the implant) rather than the 6000 cGy intended (4000 from external beam and 2000 from the implant). On October 11, the attending physician in radiation oncology reviewed the radiation therapy calculations and verified with staff the actual administered dose. A telephone report was made to the **[Identify State Health Department]** on October 12, 1993, and an on-site investigation by State staff was conducted on

NOTE: Emphasis added [bold] to clarify specific information that should be included in the report.

Ocober 14, written report from the licensee was submitted to the State agency on October 26. A committee of professionals convened to perform a quality review. As a result of a literature and standard practice review the committee concluded that the recommended treatment for Stage II vaginal carcinoma is generally in a range of 7000-7500 cGy (7000-7500 rad) total dose with an external dose of 4000-5000 cGy (4000-5000 rad) and delivery of the remaining dose by implant. Others have recommended up to a total dose of 8500 cGy (8500 rad). This patient while receiving more than her physician initially intended, did not receive a dose markedly beyond recommended treatment for her disease. The dose was within an acceptable range, therefore, it is not anticipated that any complications beyond those normally seen with treatment for this therapy will occur. However, the patient will be closely monitored for any complications and appropriate treatment will be provided. The patient had been notified of the event by the physician on October 20. A letter confirming the discussion of the the event was also sent to the patient.

Health effect to patient

Patient notification

Cause or Causes - The reportable event was caused by a failure to account for the previously administered external beam therapy. The incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment.

Actions Taken to Prevent Recurrence

Licensee - As soon as the licensee's management determined that a reportable event had occurred, they formed a committee of professionals not involved in the patient's care to conduct a quality assurance review. The committee concluded that the incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment. They recommended that no brachytherapy be given without a signed, written prescription by the attending physician. The written prescription must contain information about all radiation therapy given to the patient. The medical center has adopted the committee's recommendations and has initiated training to the affected staff. This action should prevent a recurrence of a similar event.

State agency - The results of the on-site investigation by the State staff agrees with the findings of the licensee's quality assurance review. The licensee's proposal appears to be adequate to prevent recurrence.

Status

The State considers this item (open, closed).

Appendix

Glossary

DCS	The Document Control System (DCS) is an internal NRC automated document search and retrieval system, indexed by a unique identification (assession) No. for use by the staff of the NRC.
EN	The Event Notification (EN) system is an internal NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have or may affect public health and safety. Significant material events are reported to the NRC Operations Center by NRC licensees, staff of the Agreement States, other Federal agencies, and the public. The EN's are published daily through Internet.
Gray	Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
Metric Sys.	The metric system is now included in all Federal documents. All event reports should include the dual system of Units (SI) in the following order. First use the International System of Units (SI) with the English System unit equivalent following in parentheses. Spell out the first time it appears, continue with an abbreviation, (see examples below). 1000 centiGray (cGy) (1000 rad) the first time, and continue with 1000 cGy (1000 rad). 50 millisieverts (mSv) (5 rem) 730 megabecquerel (MBq) (20.4 mCi)
NMED	The Nuclear Materials Events Database (NMED), maintained by NRC, is a historical collection of incidents and events that have occurred throughout the United States involving the use of radioactive material covered under the Atomic Energy Act. This excludes events occurring at nuclear power plants.
NRC Ops Center	The NRC Operations Center in Rockville, MD, serves as the focal coordination point for communicating with NRC licensees, State agencies, and other Federal agencies about operating events in both the nuclear reactor and nuclear material industry. The Operations Center is staffed 24 hours a day by an NRC Headquarters Operations Officer (HOO), who is trained to receive, evaluate, and respond to events reported to the Operations Center.
PN	Events reports that appear to have health and safety significance or major public or media interest are summarized and presented in Preliminary

Notification (PN) reports. These reports are available to the public through Internet.

Rad — Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/grams or 0.01 joule/kilogram (0.01 gray)

Rem — Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem. is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

Sievert — Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem.).

Reference Manual

The following is a list of NRC manuals and procedures that contain additional information on event response and abnormal occurrences. Additionally information is provided on the NRC Region contact for Agreement State issues, the Federal Radiological Emergency Response Plan (FRERP), and the Radiation Emergency Assistance Center (REACTS) along with a telephone number.

NRC Management Directives

8.1	Abnormal Occurrence Reporting Procedures
8.10	NRC Medical Event Assessment Program

NRC Inspection Manual (Series 1300, Incident Response)

1300	Incident Response Actions - Responsibility and Authority (84-080
1301	Response to Non-Emergency Incidents Involving Radioactive Material (96-022)
1302	Action Levels for Radiation Exposures and Contamination Associated with Material Events Involving Members of the Public (94-004)
1303	Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE) (95-009)
1330	Response to Transportation Accidents Involving Radioactive Materials (84-22)
1360	Use of Physician and Scientific Consultants in the Medical Consultant Program (94-013)

NRC Inspection Procedures Manual, (Series 8700, Material Safety Inspection)

87103	Inspection of Materials Licensees Involved in an Incident Bankruptcy Filing (97-008)

FRERP — The Commission is the lead federal agency for response to any event involving NRC-licensed Atomic Energy Act material under the Federal Radiological Emergency Response Plan (FRERP), which includes other federal agencies, i.e. Department of Energy (DOE), Environmental Protection Agency (EPA), Federal Emergency Response Administration (FEMA). FRERP covers any peacetime radiological emergency that has actual, potential or perceived radiological consequences within the United States.

REACTS — The Radiation Emergency Assistance Center/Training Site (REACTS), is a Department of Energy (DOE) resource headquartered in Oak Ridge, Tennessee. REACTS is available 24 hours a day to provide medical and radiological assistance either from the REACTS facility or the accident site. Additionally, REACTS maintains a listing of other professionals throughout the country who are recognized as having highly specialized expertise and equipment to manage a particular area of concern.

RSAO — The Regional State Agreements Officer (RSAO) is a designated staff member, in an NRC regional office, who serves as the point of contact for the region and the Office of State Programs regarding Agreement State radiation control programs, and who participates in technical reviews of Agreement State radiation control programs.

ATTACHMENT

8

DRC - MEDICAL MISADMINISTRATION REPORT

4.8

MEDICAL MISADMINISTRATION REPORT

TO: (Executive Secretary, Utah Radiation Control Board)	FROM: (License No., Name, Address, Phone No.)
William J. Sinclair, Director Utah Division of Radiation Control 168 North 1950 West P.O. Box 144850 Salt Lake City, Utah 84114-4850 (801)536-4250 VOX (801)533-4097 FAX	LICENSE NO. U T -

Referring Physician Name:		MONTH	DAY	YEAR
	EVENT DATE			
	WRITTEN REPORT DATE			

Phone Report Made		Physician Notified		Patient Notified		Event Record Filed	

		SODIUM IODINE, I-125 Or I-131, >30 MICROCURIES
		Wrong Patient
		Wrong Radiopharmaceutical
		Administered Dose Differs From Prescribed Dose By > 20% And Difference Exceeds 30 Microcuries
		THERAPEUTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN I-125 Or I-131
		Wrong Patient
		Wrong Radiopharmaceutical
		Wrong Route Of Administration
		Administered Dose Differs From Prescribed Dose By > 20%
		STEREOTACTIC RADIOSURGERY (Gammaknife)
		Wrong Patient
		Wrong Treatment Site
		Administered Dose Differs From Prescribed Dose By More Than 10%
		TELETHERAPY
		Wrong Patient
		Wrong Mode Of Treatment
		Wrong Treatment Site
		Administered Dose Differs From Prescribed Dose By More Than 10% If There Are 3 Or Fewer Fractions Prescribed; Or When Weekly Calculated Administered Dose Exceeds Prescribed Dose By > 30%; Or When Calculated Total Administered Dose Differs From Prescribed Dose By > 20%
		BRACHYTHERAPY
		Wrong Patient
		Wrong Radionuclide
		Wrong Treatment Site
		Leaking Source
		One Or More Sources Not Removed At End Of Treatment
		Calculated Administered Dose Differs From Prescribed Dose By > 20%
		DIAGNOSTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN QUANTITIES THAT EXCEED 30 MICROCURIES OF I-125 OR I-131, OR BOTH, WHEN THE PATIENT DOSE EXCEEDS 5 REM EFFECTIVE DOSE EQUIVALENT OR 50 REM ORGAN DOSE AND INVOLVES:
		Wrong Patient
		Wrong Radiopharmaceutical
		Wrong Route Of Administration
		Administered Dose Differs From Prescribed Dosage

Instructions: Complete the form by identifying the type of medical misadministration you are reporting. Responses for a phone report, physician notification, patient notification, and event record filing may be a yes or no response. On the reverse side of this form, write an abstract of the misadministration. Include a brief description of the event; why the event occurred; the effect on the patient; actions taken to prevent recurrence; whether the patient or the patient's responsible relative or guardian was informed, and if not, why not; and if the patient was notified, what information was provided to the patient.

SIGNATURE		DATE	

ABSTRACT

ATTACHMENT

9

NRC - FORM
565

EVENT REPORT

NRC FORM 566 (4-94)

U. S. NUCLEAR REGULATORY COMMISSION

EVENT REPORT

APPROVED BY OMB: NO. 3150-0178
EXPIRES: 04/30/97

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 1 HOUR. THIS INFORMATION IS REQUESTED TO ASSESS MATERIALS EVENTS AND EVALUATE ACTIONS NECESSARY TO PREVENT THEIR RECURRENCE. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0178), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

LICENSEE	CITY AND STATE	ORIGINAL ITEM NUMBER
TYPE OF LICENSE *(i.e., Field Radiography, Private Practice Medical, etc.)*	LICENSE NUMBER	THIS ITEM NUMBER

ABNORMAL OCCURRENCE	FOLLOW-UP REPORT	ISOTOPE	TYPE OF ISOTOPE	DATE OF EVENT
☐ YES ☐ NO	☐ YES		☐ AEA MATERIAL ☐ ACCELERATOR PRODUCED ☐ NORM	DATE OF THIS REPORT

AMOUNT OF RADIOACTIVE MATERIAL *(If amount of material is below exempt quantity, do not complete this form)*

☐ < 1 MILLICI	☐ 100 MILLICI - < 1 CI	☐ 10 CI - 100 CI	☐ UNKNOWN
☐ 1 MILLICI - < 100 MILLICI	☐ 1 CI - < 10 CI	☐ > 100 CI	

EVENTS INVOLVING OVEREXPOSURE

NUMBER OF OVEREXPOSURES	TYPE OF INDIVIDUAL	EVENT LOCATION	DOSE TO	DOSE	RAD	REM
SOURCE OF RADIATION ☐ EXTERNAL ☐ INTERNAL ☐ BOTH	☐ EMPLOYEE ☐ MINOR EMPLOYEE ☐ EMBRYO/FETUS ☐ PUBLIC	☐ RESTRICTED AREA ☐ UNRESTRICTED AREA ☐ CONTROLLED AREA	☐ WHOLE BODY ☐ LENS OF EYE ☐ EXTREMITY ☐ SKIN ☐ ORGAN			

☐ LEAKING SOURCE

☐ LOST OR STOLEN MATERIAL

EVENT	EVENT LOCATION	PROBABLE DISPOSITION	
☐ LOST ☐ FOUND ☐ THEFT ☐ THEFT, WITH FORCE	☐ FIXED SITE ☐ TEMPORARY JOB SITE ☐ LICENSED VEHICLE ☐ COMMERCIAL CARRIER ☐ OTHER *(Specify)*	☐ WELL LOGGING RECOVERED SOURCE ☐ WELL LOGGING IRRETRIEVABLE SOURCE ☐ COMMERCIAL WASTE ☐ INCINERATOR ☐ SCRAP METAL	☐ UNKNOWN ☐ OTHER *(Specify)*

☐ RELEASE OF MATERIALS

FORM	EVENT	LOCATION
☐ SOLID ☐ LIQUID ☐ GAS	☐ SPILL ☐ TRANSPORTATION ☐ OTHER *(Specify)*	☐ RESTRICTED AREA ☐ UNRESTRICTED AREA ☐ CONTROLLED AREA

☐ EVENTS INVOLVING FACILITIES

☐ FIRE ☐ DAMAGE TO DEVICE ☐ EXPLOSION	☐ SPILL ☐ > 24-HOUR DENIAL OF ACCESS ☐ DAMAGE TO SAFETY EQUIPMENT	☐ OTHER *(Specify)*

☐ EVENTS INVOLVING GAUGES

TYPE	EVENT
☐ GENERAL LICENSE ☐ EXEMPT ☐ SPECIAL LICENSE ☐ FIXED ☐ PORTABLE	☐ SHUTTER ☐ MOISTURE/DENSITY GAUGE DAMAGE ☐ LOST/STOLEN ☐ OTHER *(Specify)*

☐ EVENTS INVOLVING RADIOGRAPHY

LOCATION	EVENT
☐ FIXED ☐ TEMPORARY JOB SITE	☐ SOURCE DISCONNECT ☐ SOURCE NOT RETURNED TO FULLY SHIELDED POSITION ☐ CABLE FAILURE ☐ FAILURE TO FOLLOW PROCEDURES

☐ EVENT INVOLVING AN IRRADIATOR	MANUFACTURER	MODEL	SERIAL NUMBER
☐ EVENTS INVOLVING TELETHERAPY			

ABSTRACT *(Include the cause of the event(s) and licensee corrective action. May be continued on the reverse side)*

ATTACHMENT

10

(PEF'S)

Performance Evaluation Factors

Attachment 10

4/98

PERFORMANCE EVALUATION FACTORS (PEF'S)

PEF's are subjective factors that aid in identification of the potential for degraded radiation safety performacne; assist inspectors in focusing on causes for degraded radiation safety performance; confirm and document inspectors' conclusions about licensee's radiation safety performance.

Licensee: _____ License Number: _____

Check each appropriate performance indicator that applies when if items of noncompliance are identified:

List of Performance Indicators

Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight	( )Y ( )N
RSO too busy with other assignments	( )Y ( )N
Insufficient staffing	( )Y ( )N
Radiation Safety Committee fails to meet or functions inadequately	( )Y ( )N
Inadequate consulting services or inadequate audits	( )Y ( )N
Users not familiar with safety procedures or license conditions	( )Y ( )N
Excessive missed surveillances	( )Y ( )N
Lack of Audits	( )Y ( )N
RSO not separated from responsibility for production activities	( )Y ( )N
Repeated failure to correct violations identified by consultant or licensee	( )Y ( )N
Failure to implement adequate corrective actions on previous violations	( )Y ( )N
Inability to readily retrieve records and documentation pertaining to licensed program	( )Y ( )N
Reportable events/misadministrations since last inspection	( )Y ( )N
Numerous diagnostic misadministrations	( )Y ( )N
Numerous repeat violations	( )Y ( )N
Financial instability of licensee	( )Y ( )N
Frequent resignation of staff	( )Y ( )N
Inability to perform all required surveys, tests, audits, etc. on time	( )Y ( )N
Lack of training documentation	( )Y ( )N
Failure to assess the performance of personnel training	( )Y ( )N
Allegations/Investigations since last inspection	( )Y ( )N
Licensee not inventorying radioactive materials	( )Y ( )N
Lack of structure to identify staff responsibilities	( )Y ( )N
Company subject to name change, developed into subsidiary, or transferred	( )Y ( )N
Failure to provide training to individuals before authorizing them to use licensed materials	( )Y ( )N
Radiation waste not being disposed of at same rate of generation	( )Y ( )N
Failure to retrain authorized users	( )Y ( )N
Inadequate RSO attention to radiation safety program	( )Y ( )N
Incomplete responses to previous identified violations	( )Y ( )N
No evidence licensee is capable of responding to radiological event	( )Y ( )N
Inadequate surveys	( )Y ( )N
RSO spends insufficient time at facility	( )Y ( )N
Identified violations similar to those previously identified	( )Y ( )N
Licensee not familiar with safety procedures, license requirements, URCR, or DOT regulations	( )Y ( )N

COMMENTS: _____

_____

PERFORMANCE INDICATORS
Page 2

Evaluation of Performance Indicators

Number of Performance Indicators identified: _____

Inspectors level of concern in licensee's potential for degraded safety performance:

___	No Concern	(<2 PEF's)
___	Concern	(≥2 PEF's)
___	Significant Concern	(≥3 PEF's)
___	Great Concern	(≥4 PEF's)

Follow-up Actions Taken *(The type of follow-up action is at the discretion of the inspector.)*

___ None

___ Telephone Contacts

___ "Management paragraph"(1) added to Notice of Violation cover letter

___ Meeting with licensee management

___ Special inspection, tailored to a particular aspect(s) of the licensee's radiation safety program

___ Early follow-up inspection

___ Confirmatory action letters

___ Other

(1) *The Division of Radiation Control is (concerned, significantly concerned or greatly concerned) with the implementation of your program in the area of management control in that your corrective actions were not effective and resulted in the recurrence of violation(s). Consequently, your required response to this letter should describe those specific actions planned or taken to improve the effectiveness of the management control of your licensed operations, with particular emphasis on measures currently being taken to prevent further violations.*

APPENDIX III

INSPECTION OF AGREEMENT STATE LICENSEES

A. PURPOSE

Policy and guidelines for performing inspections of Agreement State licensees working under reciprocity.

B. INSPECTION

The regional office(s) that have Nuclear Regulatory Commission jurisdiction in the area(s) in which the Agreement State licensees will operate shall take the following action:

1. FREQUENCY

Inspections of Agreement State licensees operating under the general license in 10 CFR 150.20 should be conducted using the same provisions used for equivalent NRC-licensed activities, except as specifically defined in this chapter. These provisions include, but are not limited to, inspection processes and inspection reports as defined in NRC Manual Chapter 2800 (MC 2800). The inspection frequencies for reciprocity licensees are not subject to the provisions in MC 2800 and are not to be extended for good licensee performance.

The percentage of reciprocity licensees to be inspected each year by program code and priority should be as follows with priorities 1 through 3 as Core Inspections and the remaining priorities as non-Core Inspections:

Priority 1 program codes - 50 percent of licensees inspected each year

100 percent of all service licensees who perform teletherapy and panoramic irradiator source installations, changes, and removals are also to be inspected each year.

Priority 2 program codes - 50 percent of licensees inspected each year

Priority 3 program codes - 30 percent of licensees inspected each year

Priority 4 program codes - 25 percent of licensees inspected each year

All other program codes - 10 percent of licensees inspected each year

NOTE: The percentages of inspections of reciprocity licensees are based on the number of initial NRC Form 241 requests received for processing by each regional office.

NOTE: In cases where a licensee performs reciprocity activities in several regions, the region with the first opportunity to inspect the licensee at a work site or the home office should do so. The completed inspection should be recorded as a completion for the inspecting region. The inspecting region should notify the regional office responsible for the area in which the Agreement State licensee is located.

2. LOCATION

Inspections of Agreement State licensees operating under reciprocity in areas of NRC jurisdiction pose many difficulties such as short lead time and logistics. Therefore, to meet NRC's inspection goal, the following inspection scenarios, in decreasing preference from option a. to option d. should be followed for the inspection of reciprocity activities:

a. Conduct unannounced inspections of actual field work locations.

b. Conduct announced inspections of actual field work locations.

c. Conduct unannounced inspections of the licensee's home office after completion of reciprocity activities (if unable to inspect actual field work location) and after notifying the Agreement State.

d. Conduct announced inspections of the licensee's home office after completion of reciprocity activities (if unable to inspect actual field work location) and after notifying the Agreement State.

C. INSPECTION REPORTS AND ENFORCEMENT ACTION

1. Field notes (unless escalated enforcement action is anticipated) shall be prepared for all inspections of Agreement State licensee activities. The inspecting region should enter the inspection documentation into the Inspection Followup System, and enter any pertinent information (as described in the Reciprocity Tracking system (RTS) Users Manual) about inspections and escalated enforcement actions into the RTS.

Note: For assist inspections, follow the procedures in MC 2800.

Note: Inspections of the licensee's home office should be entered into the first entry for the licensee with one entry per inspection.

2. The official record copy of the inspection documentation with the authorized NRC Form 241 shall be assigned the appropriate Regulatory Information Distribution System (RIDS) code and sent to NUDOCS/RIDS for processing.

3. "General Policy and Procedure for NRC Enforcement Actions," NUREG-1600, shall be used as the policy and criteria for taking enforcement actions against the licensee.

4. Copies of the enforcement correspondence shall be sent to:

   a. The Agreement State authority issuing the license under which the Agreement State licensee is operating:

   b. The NRC regional office in which the Agreement State is located:

   c. Other distribution in accordance with existing procedures.

5. Obtain the next available inspection report number from the Inspection Report Tracking System and record it in the comment field in RTS.

END

POLICY ON INSPECTION REVIEWS

1. Written field reports will be used to outline the scope of a radiation safety inspection. Inspectors will use field reports to document observations and any apparent violations of applicable requirements. Compliance History (summary of violations since the initial inspection) will also accompany the report as well as be updated in the database. A routing sheet (see attachment) with the inspector's and peer reviewer's comments as well as their signature and date will be entered on the routing sheet.

2. Each inspection report will be reviewed by a second inspector before being submitted for the Sections Manager's signature and subsequent filing.

3. The Section Manager will maintain a log of completed inspections and shall perform a management review of approximately every tenth inspection.

4. Supervisory personnel will accompany each inspector on at least on inspection per year.

INSPECTION ROUTING SHEET

Licensee: _____ License #: UT _____

Insp. Type: _____ Supvsr Accomp: _____ **DATE**

1. Conducted by: _____
2. Prepared by: _____
3. Reviewed by: CLARK GWYN JULIE PHILIP _____

Reviewer's Comments: _____

_____

_____

_____

Next Inspection: Next Insp. Type:

SUPERVISORY REVIEW: INSPECTIONS AND INCIDENTS

Conducted by: _____ Date: _____

Y N N/A Opening with management
Y N N/A Operations observed
Y N N/A Non-compliance recorded
Y N N/A NOV Letter drafted: Non-compliance correct
Y N N/A Posting/Labeling reviewed
Y N N/A Leak Test dates reviewed
Y N N/A Dosimetry reviewed
Y N N/A Radioactive materials inventory reviewed
Y N N/A Bioassay review adequate
Y N N/A Records review adequate [ ] slice included
Y N N/A Quality assurance reviewed
Y N N/A Radiation Safety Committee meetings reviewed
Y N N/A Procedures reviewed
Y N N/A Instruments adequate for scope of program
Y N N/A Wipes and surveys adequate
Y N N/A Instrumentation and procedures adequate
Y N N/A Training adequate
Y N N/A Instrumentation calibration adequate and timely
Y N N/A ALARA being practiced
Y N N/A Inspectors comments and recommendations in letter
Y N N/A _____
Y N N/A _____

General Statement of Policy and Procedure For DRC Enforcement Actions

Preface

The following statement of general policy and procedure explains the enforcement policy and procedures of the Division of Radiation Control (DRC) and the DRC staff (staff) in initiating enforcement actions, and of the Executive Secretary of the Utah Radiation Control Board in reviewing these actions. This statement is applicable to enforcement in matters involving the radiological health and safety of the public, including employees' health and safety and the environment. The Executive Secretary may deviate from this statement of policy and procedure as appropriate under the circumstances of a particular case.

I. Introduction and Purpose

The purpose of the DRC enforcement program is to support the DRC's overall safety mission in protecting the public and the environment. Consistent with that purpose, enforcement action should be used:

As a deterrent to emphasize the importance of compliance with requirements, and

To encourage prompt identification and prompt, comprehensive correction of violations.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees, who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the DRC expects.[1] Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of this enforcement policy. In no case, however, will licensees who cannot achieve and maintain adequate levels of safety be permitted to conduct licensed activities.

For purposes of this policy statement, safety means avoiding undue risk, i.e., providing reasonable assurance of adequate protection for the public in connection with the use of radioactive materials. Compliance means meeting regulatory requirements. Appendix A to this policy statement describes the nexus between safety and compliance.

II. Statutory Authority and Procedural Framework

A. Statutory Authority

The DRC's enforcement jurisdiction is drawn from the Radiation Control Act of the Utah Code 1954, as amended. Section 19-3-108 of the Act authorizes the DRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to protect health or to minimize danger to life or property. Section R313-14-15 of the Utah Administrative Code authorizes the DRC to revoke licenses under certain circumstances (e.g., for material false statements, in response to conditions that would have warranted refusal of a license on an original application, for a licensee's

failure to build or operate a facility in accordance with the terms of the permit or license, and for violation of a DRC rule). Section 19-3-109 authorizes the DRC to impose civil penalties not to exceed $5,000 per violation for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and for violations for which licenses can be revoked. Section 19-3-110 (2) authorizes the DRC to seek injunctive or other equitable relief for violation of regulatory requirements.

B. Procedural Framework

R313-14 of DRC's rules sets forth the procedures the DRC uses in exercising its enforcement authority. R313-14-15 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in R313-14-15. This rule provides that the civil penalty process is initiated by issuing a Notice of Violation and Proposed Imposition of a Civil Penalty. The licensee or other person is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the response, the civil penalty may be mitigated, remitted, or imposed. An opportunity is provided for a hearing if a civil penalty is imposed. If a civil penalty is not paid following a hearing or if a hearing is not requested, the matter may be referred to the Utah Attorney General to institute a civil action.

Information concerning an order to institute a proceeding to modify, suspend, or revoke a license or to take other action against a licensee or other person subject to the jurisdiction of the Executive Secretary is set forth in R313-14-15. The licensee or any other person adversely affected by the order may request a hearing. The DRC is authorized to make orders immediately effective if required to protect the public health, safety, or interest, or if the violation is willful. In accordance with R313-14-15 (5) a Demand for Information (Demand) may be issued to a licensee or other person subject to the Executive Secretary's jurisdiction for the purpose of determining whether an order or other enforcement action should be issued. The Demand does not provide hearing rights, as only information is being sought. A licensee must answer a Demand.

III. Responsibilities

The Executive Secretary has been delegated the authority to approve or issue all escalated enforcement actions.[2]

In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, judgment and discretion must be exercised in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to issue a Notice of Violation, or to propose or impose a civil penalty and the amount of this penalty, after considering the general principles of this statement of policy and the technical and regulatory significance of the violations and the surrounding circumstances.

With consultation or notification of the Executive Secretary, the DRC staff may depart, where

warranted in the public's interest, from this policy as provided in Section VII, "Exercise of Enforcement Discretion." The Executive Secretary shall approve all enforcement actions involving civil penalties or orders. The Executive will be consulted prior to taking action in the following situations:

(1) An action affecting a licensee's operation that requires balancing the public health and safety implications of not operating with the potential radiological or other hazards associated with continued operation;

(2) Any proposed enforcement action that involves a Severity Level I violation; and

(3) Any proposed enforcement action on which the Executive Secretary asks to be consulted.

IV. Severity of Violations

Regulatory requirements[3] have varying degrees of safety, or environmental significance. Therefore, the relative importance of each violation, including both the technical significance and the regulatory significance, is evaluated as the first step in the enforcement process. In considering the significance of a violation, the staff considers the technical significance, i.e., actual and potential consequences, and the regulatory significance. In evaluating the technical significance, risk is an appropriate consideration.

Consequently, for purposes of formal enforcement action, violations are normally categorized in terms of five levels of severity to show their relative importance. Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant regulatory concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern.

The Executive Secretary recognizes that there are other violations of minor safety or environmental concern which are below the level of significance of Severity Level IV violations. These minor violations are assigned to Severity Level V. To the extent such violations are described, they will be noted as violations of minor significance.

Appendix B provides examples and serves as guidance in determining the appropriate severity level for violations. However, the examples are neither exhaustive nor controlling. In addition, these examples do not create new requirements. Each is designed to illustrate the significance that the DRC places on a particular type of violation of DRC requirements. Each of the examples is predicated on a violation of a regulatory requirement.

The DRC reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level best suited to the significance of the particular violation. In some cases, special circumstances may warrant an adjustment to the severity level categorization.

A. Aggregation of Violations

A group of Severity Level IV violations may be evaluated in the aggregate and assigned a single, increased severity level, thereby resulting in a Severity Level III problem, if the violations have the same underlying cause or programmatic deficiencies, or the violations contributed to or were unavoidable consequences of the underlying problem. Normally, Severity Level II and III violations are not aggregated into a higher severity level.

The purpose of aggregating violations is to focus the licensee's attention on the fundamental underlying causes for which enforcement action appears warranted and to reflect the fact that several violations with a common cause may be more significant collectively than individually and may therefore, warrant a more substantial enforcement action.

B. Repetitive Violations

The severity level of a Severity Level IV violation may be increased to Severity Level III, if the violation can be considered a repetitive violation. The purpose of escalating the severity level of a repetitive violation is to acknowledge the added significance of the situation based on the licensee's failure to implement effective corrective action for the previous violation. The decision to escalate the severity level of a repetitive violation will depend on the circumstances, such as, but not limited to, the number of times the violation has occurred, the similarity of the violations and their root causes, the adequacy of previous corrective actions, the period of time between the violations, and the significance of the violations.

C. Willful Violations

Willful violations are by definition of particular concern to the Executive Secretary because the State's regulatory program is based on licensees acting with integrity and communicating with candor. Willful violations cannot be tolerated by either the Executive Secretary or a licensee. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances such that it demonstrates the seriousness of the violation thereby creating a deterrent effect within the licensee's organization. Although removal of the person is not necessarily required, substantial disciplinary action is expected.

Therefore, the severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used in this policy embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., inadvertent clerical errors in a document submitted to the DRC. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the

person involved in the violation (e.g.,. licensee official[5] or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation. However, if a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be categorized at least at a Severity Level IV.

D. Violations of Reporting Requirements

The DRC expects licensees to provide complete, accurate, and timely information and reports. Accordingly, the severity level of a violation involving the failure to make a required report to the DRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report. A licensee will, on the other hand, normally be cited for a failure to report a condition or event if the licensee knew of the information to be reported, but did not recognize that it was required to make a report.

V. Predecisional Enforcement Conferences

Whenever the DRC has learned of the existence of a potential violation for which escalated enforcement action appears to be warranted, the DRC may provide an opportunity for a predecisional enforcement conference with the licensee before taking enforcement action. The purpose of the conference is to obtain information that will assist the DRC in determining the appropriate enforcement action, such as: (1) a common understanding of facts, root causes and missed opportunities associated with the apparent violations, (2) a common understanding of corrective actions taken or planned, and (3) a common understanding of the significance of issues and the need for lasting comprehensive corrective action.

If the DRC concludes that it has sufficient information to make an informed enforcement decision, a conference will not normally be held. If a conference is not held, the licensee may be requested to provide a written response to describe the licensee's views on the apparent violations and their root causes and a description of planned or implemented corrective actions. However, if the DRC has sufficient information to conclude that a civil penalty is not warranted, it may proceed to issue an enforcement action without first obtaining the licensee's response.

During a predecisional enforcement conference, the licensee will be given an opportunity to provide information consistent with the purpose of the conference, including an explanation to the DRC of the immediate corrective actions (if any) that were taken following identification of the potential violation or nonconformance and the long-term comprehensive actions that were taken or will be taken to prevent recurrence. Licensees will be told when a meeting is a predecisional enforcement

conference.

A predecisional enforcement conference is a meeting between the DRC and the licensee. Conferences are normally held in the DRC offices and are normally open to public observation. Conferences will not normally be open to the public if the enforcement action being contemplated:

(1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

(2) Involves significant personnel failures where the DRC has requested that the individual(s) involved be present at the conference;

(3) Is based on the findings of a DRC Investigation report that has not been publicly disclosed; or

(4) Involves information which could be considered protected under the Government Records Access and Management Act;

In addition, conferences will not normally be open to the public if:

(5) The conference involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing the exposed individual's name; or

(6) The conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility.

Notwithstanding the above normal criteria for opening or closing conferences, they may either be open or closed to the public after balancing the benefit of the public's observation against the potential impact on the Executive Secretary's decision-making process in a particular case. The DRC will notify the licensee that the conference will be open to public observation and the DRC may issue a press release that a predecisional enforcement conference has been scheduled and that it is open to public observation.

The public attending open conferences may observe but may not participate in the conference. It is noted that the purpose of conducting open conferences is not to maximize public attendance, but rather to provide the public with opportunities to be informed of DRC activities consistent with the DRC's ability to exercise its regulatory and safety responsibilities. Therefore, members of the public will be allowed access to the DRC offices to attend open enforcement conferences. These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" be permitted, and that disruptive persons may be removed. The open conference will be terminated if disruption interferes with a successful conference. DRC's Predecisional Enforcement Conferences (whether open or closed) normally will be held at the DRC's offices and not in the vicinity of the licensee's facility.

For a case in which DRC staff finds that discrimination has occurred, the investigation report may be made public, subject to withholding certain information (i.e., after appropriate redaction), in which case the associated predecisional enforcement conference will normally be open to public observation. In a conference where a particular individual is being considered potentially responsible for the discrimination, the conference will remain closed. In either case (i.e., whether the conference is open or closed), the employee or former employee who was the subject of the alleged discrimination (hereafter referred to as "complainant") will normally be provided an opportunity to participate in the predecisional enforcement conference with the licensee/employer. This participation will normally be in the form of a complainant statement and comment on the licensee's presentation, followed in turn by an opportunity for the licensee to respond to the complainant's presentation. In cases where the complainant is unable to attend in person, arrangements will be made for the complainant's participation by telephone or an opportunity given for the complainant to submit a written response to the licensee's presentation. If the licensee chooses to forego an enforcement conference and, instead, responds to the DRC's findings in writing, the complainant will be provided the opportunity to submit written comments on the licensee's response.

Members of the public attending open conferences will be reminded that (1) the apparent violations discussed at predecisional enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by DRC employees at predecisional enforcement conferences, or the lack thereof, are not intended to represent final determinations or beliefs.

When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order, will be taken before the conference. In these cases, a conference may be held after the escalated enforcement action is taken.

VI. Enforcement Actions

This section describes the enforcement sanctions available to the DRC and specifies the conditions under which each may be used. The basic enforcement sanctions are Notices of Violation, civil penalties, and orders of various types. As discussed further in Section VI.D, related administrative actions such as Confirmatory Action Letters and Demands for Information are used to supplement the enforcement program. In selecting the enforcement sanctions or administrative actions, the DRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters.

Usually, whenever a violation of DRC requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, a Notice of Violation is the normal action.

However, circumstances regarding the violation findings may warrant discretion being exercised such that the DRC refrains from issuing a Notice of Violation or other enforcement action. (See

Section VII.B, "Mitigation of Enforcement Sanctions.")

A. Notice of Violation

A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The Notice of Violation normally requires the recipient to provide a written statement describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) corrective steps that have been taken and the results achieved; (3) corrective steps that will be taken to prevent recurrence; and (4) the date when full compliance will be achieved. The DRC may waive all or portions of a written response to the extent relevant information has already been provided to the DRC in writing or documented in a DRC inspection report. The DRC may require responses to Notices of Violation to be under oath. Normally, responses under oath will be required only in connection with Severity Level I, II, or III violations or orders.

The DRC uses the Notice of Violation as the usual method for formalizing the existence of a violation. Issuance of a Notice of Violation is normally the only enforcement action taken, except in cases where the criteria for issuance of civil penalties and orders, as set forth in Sections VI.B and VI.C, respectively, are met.

B. Civil Penalty

A civil penalty is a monetary penalty that may be imposed for violation of (1) certain specified licensing provisions of the Act or Administrative Rules or orders; or (2) any requirement for which a license may be revoked. Civil penalties are designed to deter future violations both by the involved licensee as well as by other licensees conducting similar activities and to emphasize the need for licensees to identify violations and take prompt comprehensive corrective action.

Civil penalties may be appropriate for Severity Level IV violations and are considered for Severity Level III violations. In addition, civil penalties will normally be assessed for Severity Level I and II violations.

Civil penalties are used to encourage prompt identification and prompt and comprehensive correction of violations, to emphasize compliance in a manner that deters future violations, and to serve to focus licensees' attention on violations of significant regulatory concern.

Although management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of management involvement may not be used to mitigate a civil penalty. Allowing mitigation in the latter case could encourage the lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

1. Base Civil Penalty

The DRC imposes different levels of penalties for different severity level violations. Table 1 shows the base civil penalties for radioactive materials programs. The structure of this table generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Regarding

the secondary factor of ability of licensees to pay the civil penalties, it is not the DRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of the penalties take into account a licensee's ability to pay. In determining the amount of civil penalties for licensees for whom the table does not reflect the ability to pay or the gravity of the violation, the DRC will consider as necessary an increase or decrease on a case-by-case basis. Normally, if a licensee can demonstrate financial hardship, the DRC will consider payments over time, including interest, rather than reducing the amount of the civil penalty. However, where a licensee claims financial hardship, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees.

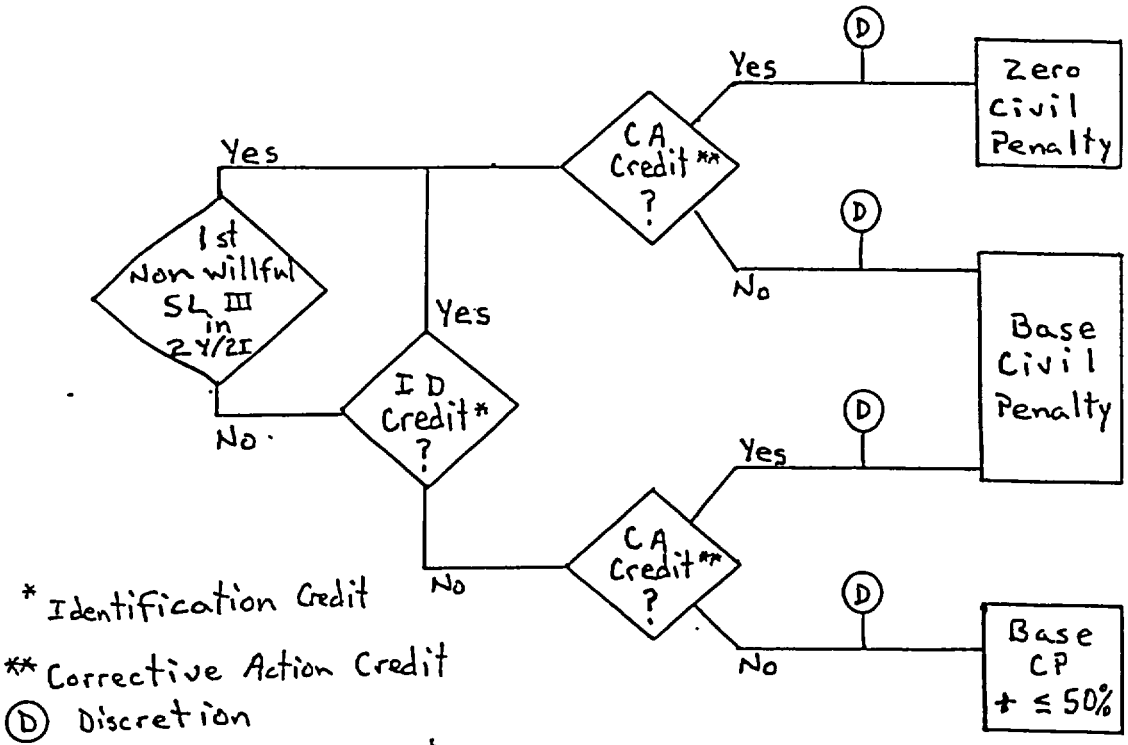
TABLE 1

Severity Level I	$5,000
Severity Level II	$4,000
Severity Level III	$2,500
Severity Level IV	$ 750
Severity Level V	$ 250

2. *Civil Penalty Assessment*

In an effort to (1) emphasize the importance of adherence to requirements and (2) reinforce prompt self-identification of problems and root causes and prompt and comprehensive correction of violations, the DRC reviews each proposed civil penalty on its own merits and, after considering all relevant circumstances, may adjust the base civil penalties shown in Table 1 as described below.

The civil penalty assessment process considers four decisional points: (a) whether the licensee has had any previous escalated enforcement action during the past 2 years or past 2 inspections, whichever is longer; (b) whether the licensee should be given credit for actions related to identification; (c) whether the licensee's corrective actions are prompt and comprehensive; and (d) whether, in view of all the circumstances, the matter in question requires the exercise of discretion. Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or a base civil penalty escalated by 50%. The flow chart presented below is a graphic representation of the civil penalty assessment process.



a. Initial Escalated Action

When the DRC determines that a non-willful Severity Level IV violation has occurred, and the licensee has not had any previous escalated actions during the past 2 years or 2 inspections, whichever is longer, the DRC will consider whether the licensee's corrective action for the present violation is reasonably prompt and comprehensive (see the discussion under Section VI.B.2.c, below). Using 2 years as the basis for assessment is expected to cover most situations, but considering a slightly longer or shorter period might be warranted based on the circumstances of a particular case. The starting point of this period should be considered the date when the licensee was put on notice of the need to take corrective action. For a licensee-identified violation or an event, this would be when the licensee is aware that a problem or violation exists requiring corrective action. For an DRC-identified violation, the starting point would be when the DRC puts the licensee on notice, which could be during the inspection, at the inspection exit meeting, or as part of post-inspection communication.

If the corrective action is judged to be prompt and comprehensive, a Notice of Violation normally should be issued with no associated civil penalty. If the corrective action is judged to be less than prompt and comprehensive, the Notice of Violation normally should be issued with a base civil penalty.

b. Credit for Actions Related to Identification

(1) If a Severity Level I or II violation or a willful Severity Level III violation has occurred--or if, during the past 2 years or 2 inspections, whichever is longer, the licensee has been issued at least one other escalated action--the civil penalty assessment should normally

consider the factor of identification in addition to corrective action (see the discussion under Section VI.B.2.c, below). As to identification, the DRC should consider whether the licensee should be given credit for actions related to identification.

In each case, the decision should be focused on identification of the problem requiring corrective action. In other words, although giving credit for *Identification* and *Corrective Action* should be separate decisions, the concept of *Identification* presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed. The decision on *Identification* requires considering all the circumstances of identification including:

(i) Whether the problem requiring corrective action was DRC-identified, licensee-identified, or revealed through an event[6];

(ii) Whether prior opportunities existed to identify the problem requiring corrective action, and if so, the age and number of those opportunities;

(iii) Whether the problem was revealed as the result of a licensee self-monitoring effort, such as conducting an audit, a test, a surveillance, a design review, or troubleshooting;

(iv) For a problem revealed through an event, the ease of discovery, and the degree of licensee initiative in identifying the root cause of the problem and any associated violations;

(v) For DRC-identified issues, whether the licensee would likely have identified the issue in the same time-period if the DRC had not been involved;

(vi) For DRC-identified issues, whether the licensee should have identified the issue (and taken action) earlier; and

(vii) For cases in which the DRC identifies the overall problem requiring corrective action (e.g., a programmatic issue), the degree of licensee initiative or lack of initiative in identifying the problem or problems requiring corrective action.

(2) Although some cases may consider all of the above factors, the importance of each factor will vary based on the type of case as

discussed in the following general guidance:

(i) **Licensee-Identified.** When a problem requiring corrective action is licensee-identified (i.e., identified before the problem has resulted in an event), the DRC should normally give the licensee credit for actions related to identification, regardless of whether prior opportunities existed to identify the problem.

(ii) **Identified Through an Event.** When a problem requiring corrective action is identified through an event, the decision on whether to give the licensee credit for actions related to identification normally should consider the ease of discovery, whether the event occurred as the result of a licensee self-monitoring effort (i.e., whether the licensee was "looking for the problem"), the degree of licensee initiative in identifying the problem or problems requiring corrective action, and whether prior opportunities existed to identify the problem.

Any of these considerations may be overriding if particularly noteworthy or particularly egregious. For example, if the event occurred as the result of conducting a surveillance or similar self-monitoring effort (i.e., the licensee was looking for the problem), the licensee should normally be given credit for identification. As a second instance, even if the problem was easily discovered (e.g., revealed by a large spill of liquid), the DRC may choose to give credit because noteworthy licensee effort was exerted in ferreting out the root cause and associated violations, or simply because no prior opportunities (e.g., procedural cautions, post-maintenance testing, quality control failures, readily observable parameter trends, or repeated or locked-in annunciator warnings) existed to identify the problem.

(iii) **DRC-Identified.** When a problem requiring corrective action is DRC-identified, the decision on whether to give the licensee credit for actions related to *Identification* should normally be based on an additional question: should the licensee have reasonably identified the problem (and taken action) earlier?

In most cases, this reasoning may be based simply on the ease

of the DRC inspector's discovery (e.g., conducting a walk through survey, observing in the facility, performing a confirmatory DRC radiation survey, or finding a safety device out of service). In some cases, the licensee's missed opportunities to identify the problem might include a similar previous violation, DRC notices, internal audits, or readily observable trends.

If the DRC identifies the violation but concludes that, under the circumstances, the licensee's actions related to *Identification* were not unreasonable, the matter would be treated as licensee-identified for purposes of assessing the civil penalty. In such cases, the question of *Identification* credit shifts to whether the licensee should be penalized for DRC's identification of the problem.

(iv) **Mixed Identification.** For "mixed" identification situations (i.e., where multiple violations exist, some DRC-identified, some licensee-identified, or where the DRC prompted the licensee to take action that resulted in the identification of the violation), the DRC's evaluation should normally determine whether the licensee could reasonably have been expected to identify the violation in the DRC's absence. This determination should consider, among other things, the timing of the DRC's discovery, the information available to the licensee that caused the DRC concern, the specificity of the DRC's concern, the scope of the licensee's efforts, the level of licensee resources given to the investigation, and whether the DRC's path of analysis had been dismissed or was being pursued in parallel by the licensee.

In some cases, the licensee may have addressed the isolated symptoms of each violation (and may have identified the violations), but failed to recognize the common root cause and taken the necessary comprehensive action. Where this is true, the decision on whether to give licensee credit for actions related to *Identification* should focus on identification of *the problem requiring corrective action* (e.g., the programmatic breakdown). As such, depending on the chronology of the various violations, the earliest of the individual violations might be considered missed opportunities for the licensee to have identified the larger problem.

(v) **Missed Opportunities to Identify.** Missed opportunities include prior notifications or missed opportunities to identify or prevent violations such as (1) through normal surveillances, audits, or quality assurance (QA) activities; (2) through prior notice i.e., specific DRC notification; or (3) through other reasonable indication of a potential problem or violation, such as observations of employees, and failure to take effective corrective steps. It may include findings of the DRC or the licensee made at other facilities operated by the licensee where it is reasonable to expect the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue. In assessing this factor, consideration will be given to, among other things, the opportunities available to discover the violation, the ease of discovery, the similarity between the violation and the notification, the period of time between when the violation occurred and when the notification was issued, the action taken (or planned) by the licensee in response to the notification, and the level of management review that the notification received (or should have received).

The evaluation of missed opportunities should normally depend on whether the information available to the licensee should reasonably have caused action that would have prevented the violation. Missed opportunities is normally not applied where the licensee appropriately reviewed the opportunity for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.

In some situations the missed opportunity is a violation in itself. In these cases, unless the missed opportunity is a Severity Level III violation in itself, the missed opportunity violation may be grouped with the other violations into a single Severity Level III "problem." However, if the missed opportunity is the *only* violation, then it should not normally be counted twice (i.e., both as the violation and as a missed opportunity--"double counting") unless the number of opportunities missed was particularly significant.

The timing of the missed opportunity should also be considered. While a rigid time-frame is unnecessary, a 2-year period should generally be considered for consistency in

implementation, as the period reflecting relatively current performance.

(3) When the DRC determines that the licensee should receive credit for actions related to *Identification*, the civil penalty assessment should normally result in either no civil penalty or a base civil penalty, based on whether *Corrective Action* is judged to be reasonably prompt and comprehensive. When the licensee is *not* given credit for actions related to *Identification*, the civil penalty assessment should normally result in a Notice of Violation with either a base civil penalty or a base civil penalty escalated by up to 50%, depending on the quality of *Corrective Action*, because the licensee's performance is clearly not acceptable.

c. *Credit for Prompt and Comprehensive Corrective Action*

The purpose of the *Corrective Action* factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety and compliance with the license, rule(s), or other requirement(s); and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes.

Regardless of other circumstances (e.g., past enforcement history, identification), the licensee's corrective actions should always be evaluated as part of the civil penalty assessment process. As a reflection of the importance given to this factor, a DRC judgment that the licensee's corrective action has not been prompt and comprehensive will always result in issuing at least a base civil penalty.

In assessing this factor, consideration will be given to the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action), the adequacy of the licensee's root cause analysis for the violation, and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern). Even in cases when the DRC, at the time of the enforcement conference, identifies additional peripheral or minor corrective action still to be taken, the licensee may be given credit in this area, as long as the licensee's actions addressed the underlying root cause and are considered sufficient to prevent recurrence of the violation and similar violations.

Normally, the judgment of the adequacy of corrective actions will hinge on whether the DRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive corrective action. This will normally be judged at the time of the predecisional enforcement conference (e.g., by outlining substantive additional areas where corrective action is needed). Earlier informal discussions between the licensee and DRC inspectors or management may result in improved corrective action, but should not normally be a basis to deny credit for *Corrective Action*. For cases in which the licensee does not get credit for actions related to *Identification* because the DRC identified the problem, the assessment of the licensee's corrective action should begin from the time when the DRC put the licensee on notice of the problem. Notwithstanding eventual good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, corrective action would not be considered prompt and comprehensive.

d. Exercise of Discretion

As provided in Section VII, "Exercise of Discretion," discretion may be exercised by either escalating or mitigating the amount of the civil penalty determined after applying the civil penalty adjustment factors to ensure that the proposed civil penalty reflects the DRC's concern regarding the violation at issue and that it conveys the appropriate message to the licensee. However, in no instance will a civil penalty for any one violation exceed $5,000 per day.

C. Orders

An order is a written DRC directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take such other action as may be proper (see R313-14-15(3). Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate for Severity Level I, II, III, or IV violations. Orders may be issued as follows:

1. License Modification orders are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.

2. Suspension Orders may be used:
   (a) To remove a threat to the public health and safety, common defense and security, or the environment;

   (b) To stop facility construction when,
      (i) Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component; or
      (ii) The licensee's quality assurance program implementation is not

adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

(d) When the licensee interferes with the conduct of an inspection or investigation; or

(e) For any reason not mentioned above for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

3. Revocation Orders may be used:
   (a) When a licensee is unable or unwilling to comply with DRC requirements;

   (b) When a licensee refuses to correct a violation;

   (c) When licensee does not respond to a Notice of Violation where a response was required; or

   (d) When a licensee refuses to pay an applicable fee under the Utah Radiaiton Control rules.

4. Cease and Desist Orders may be used to stop an unauthorized activity that has continued after notification by the DRC that the activity is unauthorized.

Unless a separate response is warranted pursuant to R313-14-15 (1), a Notice of Violation need not be issued where an order is based on violations described in the order. The violations described in an order need not be categorized by severity level.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the DRC believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show why the order should not be issued in the proposed manner by way of a Demand for Information.

D. Related Administrative Actions

In addition to the formal enforcement actions, Notices of Violation, civil penalties, and orders, the DRC also uses administrative actions, such as Bullitins, Information Notices, Confirmatory Action

Letters, and Demands for Information to supplement its enforcement program. The DRC expects licensees to adhere to any obligations and commitments resulting from these actions and will not hesitate to issue appropriate orders to ensure that these obligations and commitments are met.

1. Bulletins and Information Notices are written notificaitons to groups of licensees identifying specific problems and calling for or recommending specific actions on their part.

2. Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety or the environment.

3. Demands for Information are demands for information from licensees or other persons for the purpose of enabling the DRC to determine whether an order or other enforcement action should be issued.

VII. Exercise of Discretion

Notwithstanding the normal guidance contained in this policy, as provided in Section III, "Responsibilities," the DRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions within the Executive Secretary's authority to ensure that the resulting enforcement action appropriately reflects the level of DRC concern regarding the violation at issue and conveys the appropriate message to the licensee.

A. Escalation of Enforcement Sanctions

The DRC considers violations categorized at Severity Level I, II, or III to be of significant regulatory concern. If the application of the normal guidance in this policy does not result in an appropriate sanction, the DRC may apply its full enforcement authority where the action is warranted. DRC action may include (1) escalating civil penalties, (2) issuing appropriate orders, and (3) assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of $5,000 per violation, per day.

1. ***Civil penalties.***
   Notwithstanding the outcome of the normal civil penalty assessment process addressed in Section VI.B, the DRC may exercise discretion by either proposing a civil penalty where application of the factors would otherwise result in zero penalty or by escalating the amount of the resulting civil penalty to ensure that the proposed civil penalty reflects the significance of the circumstances and conveys the appropriate regulatory message to the licensee. The Executive Secretary will be notified if the deviation in the amount of the civil penalty proposed under this discretion from the amount of the civil penalty assessed under the normal process is more than 50% higher than the base civil penalty shown in Table 1. Examples when this discretion should be considered include, but are not limited to the following:

(a) Problems categorized at Severity Level I or II;

(b) Overexposures, or releases of radiological material in excess of DRC requirements;

(c) Situations involving particularly poor licensee performance, or involving willfulness;

(d) Situations when the licensee's previous enforcement history has been particularly poor, or when the current violation is directly repetitive of an earlier violation;

(e) Situations when the violation results in a substantial increase in risk, including cases in which the duration of the violation has contributed to the substantial increase;

(f) Situations when the licensee made a conscious decision to be in noncompliance in order to obtain an economic benefit; or

(g) Cases involving the loss of a source. In addition, unless the licensee self-identifies and reports the loss to the DRC, these cases should normally result in a civil penalty in an amount at least in the order of the cost of an authorized disposal of the material or of the transfer of the material to an authorized recipient.

2. *Orders.*
The DRC may, where necessary or desirable, issues orders in conjunction with or in lieu of civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations.

3. *Assessment of Civil Penalties for Continuing Violations.*
In order to recognize the added technical safety significance or regulatory significance for those cases where a very strong message is warranted for a significant violation that continues for more than one day, the DRC may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit of $5,000 for each occurrence the violation continues. The DRC may exercise this discretion if a licensee was aware or clearly should have been aware of a violation, or if the licensee had an opportunity to identify and correct the violation but failed to do so.

B. Mitigation of Enforcement Sanctions

The DRC may exercise discretion and refrain from issuing a civil penalty and/or a Notice of Violation, if the outcome of the normal process described in Sections VI.A and VI.B does not result in a sanction consistent with an appropriate regulatory message. In addition, even if the DRC exercises this discretion, when the licensee failed to make a required report to the DRC, a separate enforcement action will normally be issued for the licensee's failure to make a required report. The approval of the Executive Secretary is required for exercising discretion of the type described in Section VII.B.1.b where a willful violation is involved, and of the types described in Sections VII.B.2 through VII.B.5. Examples when discretion should be considered for departing from the normal approach in Sections VI.A and VI.B include, but are not limited to the following:

1. *Licensee-Identified Severity Level IV Violations.*

The DRC, with the approval of the Executive Secretary, may refrain from issuing a Notice of Violation for a Severity Level IV violation that is documented in an inspection report or official field notes and described therein as a Non-Cited Violation (NCV) provided that the documentation includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was identified by the licensee;

(b) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past 2 years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(c) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(d) It was not a willful violation or if it was a willful violation;

(i) The information concerning the violation, if not required to be reported, was promptly provided to appropriate DRC personnel;

(ii) The violation involved the acts of a low-level individual (and not a licensee official as defined in Section IV.C);

(iii) The violation appears to be the isolated action of the employee without management involvement and the violation was not caused by lack of management oversight as evidenced by either a history of isolated willful violations or a lack of adequate audits or supervision

of employees; and

(iv) Significant remedial action commensurate with the circumstances was taken by the licensee such that it demonstrated the seriousness of the violation to other employees, thereby creating a deterrent effect within the licensee's organization. Although removal of the employee from licensed activities is not necessarily required, substantial disciplinary action is expected.

3. *Violations Involving Old Design Issues.*
The DRC may refrain from proposing a civil penalty for a Severity Level II or III violation involving a past problem, such as in engineering, design, or installation, provided that the violation is documented in an inspection report or official field notes that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was a licensee-identified as a result of its voluntary initiative;

(b) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification (this action should involve expanding the initiative, as necessary, to identify other failures caused by similar root causes); and

(c) It was not likely to be identified (after the violation occurred) by routine licensee efforts such as normal surveillance or quality assurance (QA) activities.

In addition, the DRC may refrain from issuing a Notice of Violation for a Severity Level II, III, or IV violation that meets the above criteria provided the violation was caused by conduct that is not reasonably linked to present performance (normally, violations that are at least 3 years old) and there had not been prior notice so that the licensee should have reasonably identified the violation earlier. This exercise of discretion is to place a premium on licensees initiating efforts to identify and correct subtle violations that are not likely to be identified by routine efforts before degraded safety systems are called upon to work.

4. *Violations Identified Due to Previous Enforcement Action.*
The DRC may refrain from issuing a Notice of Violation or a proposed civil penalty for a violation that is identified after the DRC has taken enforcement action, provided that the violation is documented in an inspection report or official field notes that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was licensee-identified as part of the corrective action for the previous enforcement action;

(b) It has the same or similar root cause as the violation for which enforcement action was issued;

(c) It does not substantially change the safety significance or the character of the regulatory concern arising out of the initial violation;

(d) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification; and

(e) It would not be categorized at Severity Level I.

5. *Violations Involving Special Circumstances.*
Notwithstanding the outcome of the normal enforcement process addressed in Section VI.A or the normal civil penalty assessment process addressed in Section VI.B, the DRC may reduce or refrain from issuing a civil penalty or a Notice of Violation for a Severity Level II, III, IV, or V violation based on the merits of the case after considering the guidance in this statement of policy and such factors as the age of the violation, the technical and regulatory significance of the violation, the clarity of the requirement, the appropriateness of the requirement, the overall sustained performance of the licensee has been particularly good, and other relevant circumstances, including any that may have changed since the violation. This discretion is expected to be exercised only where application of the normal guidance in the policy is unwarranted. In addition, the DRC may refrain from issuing enforcement action for violations resulting from matters not within a licensee's control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees and contractors. Accordingly, this policy should not be construed to excuse personnel or contractor errors.

VIII. Public Disclosure of Enforcement Actions

Enforcement actions and licensees' responses, in accordance with the Government Records Access and Management Act, II, are publicly available for inspection. In addition, press releases may be issued for orders and civil penalties and they should be issued at the same time the order or proposed imposition of the civil penalty is issued. In addition, press releases may be issued when a proposed civil penalty is withdrawn or substantially mitigated by some amount. Press releases are not normally issued for Notices of Violation that are not accompanied by orders or proposed civil penalties.

IX. Reopening Closed Enforcement Actions

If significant new information is received or obtained by DRC which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the Executive Secretary.

Appendix A: Safety and Compliance

As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. In the context of DRC's regulatory program, safety means avoiding undue risk or, stated another way, providing reasonable assurance of adequate protection for the public in connection with the use of radioactive materials.

The definition of compliance is much simpler. Compliance simply means meeting applicable regulatory requirements. The relationship between compliance and safety is discussed below.

* Safety is the fundamental regulatory objective, and compliance with DRC requirements plays a fundamental role in giving the DRC confidence that safety is being maintained. DRC requirements, including technical specifications, other license conditions, orders, and rules, have been designed to ensure adequate protection--which corresponds to "no undue risk to public health and safety"--through acceptable design, construction, operation, maintenance, modification, and quality assurance measures. In the context of risk-informed regulation, compliance plays a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid.

* Adequate protection is presumptively assured by compliance with DRC requirements. Circumstances may arise, however, where new information reveals, for example, that an unforeseen hazard exists or that there is a substantially greater potential for a known hazard to occur. In such situations, the DRC has the authority to require licensee action above and beyond existing rules to maintain the level of protection necessary to avoid undue risk to public health and safety.

* The DRC has the authority to exercise discretion to permit continued operations--despite the existence of a noncompliance--where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When non-compliances occur, the DRC must evaluate the degree of risk posed by that non-compliance to determine if specific immediate action is required. Where needed to ensure adequate protection of public health and safety, the DRC may demand immediate licensee action, up to and including a shutdown or cessation of licensed activities. In addition, in determining the appropriate action to be taken, the DRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance (i.e., the degree of pervasiveness) that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety. Based on the DRC's evaluation, the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions or assessments, such as increased oversight (e.g., increased inspection).

* Since some requirements are more important to safety than others, the Executive Secretary should use a risk-informed approach when applying DRC resources to the oversight of licensed activities (this includes enforcement).

Appendix B: Enforcement Examples

This appendix provides examples of violations as guidance in determining the appropriate severity level for violations.

Health Physics (R313-15)

This section provides examples of violations in each of four severity levels as guidance in determining the appropriate severity level for violations in the area of health physics, R313-15.[8]

A. *Severity Level I* - Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 25 rems total effective dose equivalent, 75 rems to the lens of the eye, or 250 rads to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 2.5 rems total effective dose equivalent;

3. A radiation exposure during any year of a minor in excess of 2.5 rems total effective dose equivalent, 7.5 rems to the lens of the eye, or 25 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. An annual exposure of a member of the public in excess of 1.0 rem total effective dose equivalent;

5. A release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public as described in R313-15-302(2)(b)(I); or

6. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits of R313-15-1003.

B. *Severity Level II* - Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye, or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 1.0 rem total effective dose equivalent;

3. A radiation exposure during any year of a minor in excess of 1 rem total effective dose equivalent; 3.0 rems to the lens of the eye, or 10 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. An annual exposure of a member of the public in excess of 0.5 rem total effective dose equivalent;

5. A release of radioactive material to an unrestricted area at concentrations in excess of 10 times the limits for members of the public as described in R313-15-302(2)(b)(I) (except when operation up to 0.5 rem a year has been approved by the Executive Secretary under R313-15-301(3));

6. Disposal of licensed material in quantities or concentrations in excess of five times the limits of R313-15-1003; or

7. A failure to make an immediate notification as required by R313-15-1202 (1)(a) or (1)(b).

C. *Severity Level III* - Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 0.5 rem total effective dose equivalent (except when doses are in accordance with the provisions of R313-15-208(4));

3. A radiation exposure during any year of a minor in excess of 0.5 rem total effective dose equivalent; 1.5 rems to the lens of the eye, or 5 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. A worker exposure above regulatory limits when such exposure reflects a programmatic (rather than an isolated) weakness in the radiation control program;

5. An annual exposure of a member of the public in excess of 0.1 rem total effective dose equivalent (except when operation up to 0.5 rem a year has been approved by the Executive Secretary under R313-15-301(3));

6. A release of radioactive material to an unrestricted area at concentrations in excess of two times the effluent concentration limits referenced in R313-15-302(2)(b)(I) (except when operation up to 0.5 rem a year has been approved by the Executive Secretary under R313-15-301(3));

7. A failure to make a 24-hour notification required by R313-15-1202(2) or an immediate notification required by R313-15-1201(1)(a)(I);

8. A substantial potential for exposures or releases in excess of the applicable limits in R313-15-1001 through 15-1301 whether or not an exposure or release occurs;

9. Disposal of licensed material not covered in Severity Levels I or II;

10. A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for members of the public, or that reflects a programmatic (rather than an isolated) weakness in the radiation control program;

11. Conduct of licensee activities by a technically unqualified person;

12. A significant failure to control licensed material; or.

13. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. *Severity Level IV* - Violations involving for example:

1. Exposures in excess of the limits of R313-15-201, 207, or 208 not constituting Severity Level I, II, or III violations;

2. A release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public as referenced in R313-15-302(2)(b)(I) (except when operation up to 0.5 rem a year has been approved by the Executive Secretary under R313-15-301(3));

3. A radiation dose rate in an unrestricted or controlled area in excess of 0.002 rem in any 1 hour (2 millirem/hour) or 50 millirems in a year;

4. Failure to maintain and implement radiation programs to keep radiation exposures as low as is reasonably achievable;

5. Doses to a member of the public in excess of any EPA generally applicable environmental radiation standards, such as 40 CFR Part 190;

6. A failure to make the 30-day notification required by R313-15-1201(1)(a)(ii) or 1203(1);

7. A failure to make a timely written report as required by R313-15-1201(2), 1204, or 1206;

8. A failure to report an exceedance of the dose constraint established in R313-15-101(4) or a failure to take corrective action for an exceedance, as required by R313-15-101(4); or

9. Any other matter that has more than a minor safety, health, or environmental significance.

Transportation

This section provides examples of violations in each of the four severity levels as guidance in determining the appropriate severity level for violations in the area of DRC transportation requirements[2].

A. *Severity Level I* - Violations involving for example:

1. Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that the material caused a radiation exposure to a member of the public and there was clear potential for the public to receive more than 0.1 rem to the whole body;

2. Surface contamination in excess of 50 times the DRC limit; or

3. External radiation levels in excess of 10 times the DRC limit.

B. *Severity Level II* - Violations involving for example:

1. Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that there was a clear potential for the member of the public to receive more than 0.1 rem to the whole body;

2. Surface contamination in excess of 10, but not more than 50 times the DRC limit;

3. External radiation levels in excess of five, but not more than 10 times the DRC limit; or

4. A failure to make required initial notifications associated with Severity Level I or II violations.

C. *Severity Level III* - Violations involving for example:

1. Surface contamination in excess of five but not more than 10 times the DRC limit;

2. External radiation in excess of one but not more than five times the DRC limit;

3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

(a) A significant failure to identify the type, quantity, or form of material;

(b) A failure of the carrier or recipient to exercise adequate controls; or

(c) A substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material;

4. A failure to make required initial notification associated with Severity Level III violations; or

5. A breakdown in the licensee's program for the transportation of licensed material

involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. *Severity Level IV* - Violations involving for example:

1. A breach of package integrity without external radiation levels exceeding the DRC limit or without contamination levels exceeding five times the DRC limits;
2. Surface contamination in excess of but not more than five times the DRC limit;
3. A failure to register as an authorized user of an NRC-Certified Transport package;
4. A noncompliance with shipping papers, marking, labeling, placarding, packaging or loading not amounting to a Severity Level I, II, or III violation;
5. A failure to demonstrate that packages for special form radioactive material meets applicable regulatory requirements;
6. A failure to demonstrate that packages meet DOT Specifications for 7A Type A packages; or
7. Other violations that have more than minor safety or environmental significance.

Materials Operations

This section provides examples of violations in each of the four severity levels as guidance in determining the appropriate severity level for violations in the area of fuel cycle and materials operations.

A. *Severity Level I* - Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license;
2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function;
3. A nuclear criticality accident;
4. A failure to follow the procedures of the quality management program, required by R313-32-32, that results in a death or serious injury (e.g., substantial organ impairment) to a patient;
5. A safety limit or the application being exceeded; or
6. Significant injury or loss of life due to a loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, whether radioactive material is released or not.

B. *Severity Level II* - Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license;
2. A system designed to prevent or mitigate a serious safety event being inoperable;
3. A substantial programmatic failure in the implementation of the quality management program required by R313-32-32 that results in a misadministration; or

4. The potential for a significant injury or loss of life due to a loss of control over licensed activities, including chemical processes that are integral to the licensed activity, whether radioactive material is released or not.

C. *Severity Level III* - Violations involving for example:

1. A failure to control access to licensed materials for radiation protection purposes as specified by DRC requirements;

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

3. Use of radioactive material on humans where such use is not authorized;

4. Conduct of licensed activities by a technically unqualified or uncertified person;

5. A substantial potential for exposures, radiation levels, contamination levels, or releases, including releases of toxic material caused by a failure to comply with DRC rules, from licensed or certified activities in excess of regulatory limits;

6. Substantial failure to implement the quality management program as required by R313-32-32 that does not result in a misadministration; failure to report a misadministration; or programmatic weakness in the implementation of the quality management program that results in a misadministration;

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities;

8. A failure, during radiographic operations, to have present at least two qualified individuals or to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by R313-36;

9. A failure to receive required DRC approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership; lack of an RSO or replacement of an RSO with an unqualified individual; a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet the safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance;

10. A significant failure to meet Executive Secretary requirements including a failure to notify the DRC as required by rule or license condition, substantial failure to meet Executive Secretary's standards, failure to conduct and/or complete Executive Secretary activities in accordance with rule or license condition, or failure to meet required schedules without adequate justification;

11. A system designed to prevent or mitigate a serious safety event:

(a) Not being able to perform its intended function under certain conditions (e.g., safety system not operable unless utilities available, materials or components not according to specifications); or

(b) Being degraded to the extent that a detailed evaluation would be required to determine its operability;

12. Changes in parameters that cause unanticipated reductions in margins of safety; or

13. A failure, during radiographic operations, to stop work after a pocket dosimeter is found

to have gone off-scale, or after an electronic dosimeter reads greater than 200 mrem, and before a determination is made of the individual's actual radiation exposure.

D. *Severity Level IV* - Violations involving for example:

1. A failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

2. Other violations that have more than minor safety or environmental significance;

3. Failure to follow the quality management (QM) program, including procedures, whether or not a misadministration occurs, provided the failures are isolated, do not demonstrate a programmatic weakness in the implementation of the QM program, and have limited consequences if a misadministration is involved; failure to conduct the required program review; or failure to take corrective actions as required by R313-32-32; or

4. A failure to keep the records required by R313-32-32 or R313-32-33.

Miscellaneous Matters

This section provides examples of violations in each of the four severity levels as guidance in determining the appropriate severity level for violations involving miscellaneous matters.

A. *Severity Level I* - Violations involving for example:

1. Inaccurate or incomplete information that is provided to the DRC (a) deliberately with the knowledge of a licensee official that the information is incomplete or inaccurate, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety;

2. Incomplete or inaccurate information that the DRC requires be kept by a licensee that is (a) incomplete or inaccurate because of falsification by or with the knowledge of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the DRC, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations; or

3. Information that the licensee has identified as having significant implications for public health and safety or the common defense and security ("significant information identified by a licensee") and is deliberately withheld from the Executive Secretary.

B. *Severity Level II* - Violations involving for example:

1. Inaccurate or incomplete information that is provided to the DRC (a) by a licensee official because of careless disregard for the completeness or accuracy of the information, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;

2. Incomplete or inaccurate information that the DRC requires be kept by a licensee which is (a) incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a licensee official, or (b) if the information, had it been complete and accurate when

reviewed by the DRC, likely would have resulted in regulatory action such as a show cause order or a different regulatory position; or

3. "Significant information identified by a licensee" and not provided to the Executive Secretary because of careless disregard on the part of a licensee official;

C. *Severity Level III* - Violations involving for example:

1. Incomplete or inaccurate information that is provided to the DRC (a) because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;

2. Incomplete or inaccurate information that the DRC requires be kept by a licensee that is (a) incomplete or inaccurate because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate when reviewed by the DRC, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information; or

3. A failure to provide "significant information identified by a licensee" to the Executive Secretary and not amounting to a Severity Level I or II violation;

D. *Severity Level IV* - Violations involving for example:

1. Incomplete or inaccurate information of more than minor significance that is provided to the DRC but not amounting to a Severity Level I, II, or III violation;

2. Information that the DRC requires be kept by a licensee and that is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation.

1. This policy primarily addresses the activities of DRC licensees and applicants for DRC licenses. Therefore, the term "licensee" is used throughout the policy.
2. The term "escalated enforcement action" as used in this policy means a Notice of Violation or civil penalty for any Severity Level I, II, or III violation (or problem) or any order based upon a violation.
3. The term "requirement" as used in this policy means a legally binding requirement such as a statute, rule, license condition, technical specification, or order.
4. The term "repetitive violation" or "similar violation" as used in this policy statement means a violation that reasonably could have been prevented by a licensee's corrective action for a previous violation normally occurring (1) within the past 2 years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer.
5. The term "licensee official" as used in this policy statement means a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on a license. Notwithstanding an individual's job title, severity level

categorization for willful acts involving individuals who can be considered licensee officials will consider several factors, including the position of the individual relative to the licensee's organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

6. An "event," as used here, means (1) an event characterized by an active adverse impact on equipment or personnel, readily obvious by human observation or instrumentation, or (2) a radiological impact on personnel or the environment in excess of regulatory limits, such as an overexposure, a release of radioactive material above DRC limits, or a loss of radioactive material. For example, an equipment failure discovered through a spill of liquid, a loud noise, the failure to have a system respond properly, or an annunciator alarm would be considered an event; a system discovered to be inoperable through a document review would not. Similarly, if a licensee discovered, through quarterly dosimetry readings, that employees had been inadequately monitored for radiation, the issue would normally be considered licensee-identified; however, if the same dosimetry readings disclosed an overexposure, the issue would be considered an event.

7. Discretion is not warranted when a licensee identifies a violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event. Discretion may be warranted if the licensee demonstrated initiative in identifying the violation's root cause.

8. Personnel overexposures and associated violations incurred during a life-saving or other emergency response effort will be treated on a case-by-case basis.

9. Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper and a carrier. When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

NRC INSPECTION MANUAL NMSS/URB

MANUAL CHAPTER 2801

URANIUM MILL AND 11e.(2) BYPRODUCT MATERIAL DISPOSAL SITE AND FACILITY INSPECTION PROGRAM

2801-01 PURPOSE

This chapter establishes the safety inspection program for uranium mills and 11e.(2) byproduct material disposal sites and facilities (11e.(2) sites) licensed and regulated under 10 CFR Part 40 including mills authorized to take 11e.(2) byproduct material. The disposal sites include both commercial disposal facilities and sites associated with licensed uranium mills. Included in the program are inspection procedures related to all phases of activities: construction and pre-operations, operations, and reclamation/closure. Procedures presented cover those facilities licensed and regulated in their entirety by NRC. The primary purpose of the inspection program is to obtain sufficient information through observations, personnel interviews, independent measurements, and review of facility records and procedures, to ascertain, in a timely manner, whether facility operations, and radiological and non-radiological programs regulated by the U.S. Nuclear Regulatory Commission conform with regulatory requirements and the conditions of the applicable license. As a result, the inspection program determines that uranium mills and 11e.(2) sites are managed throughout their entire life cycle in a manner that provides protection from radioactivity to employees, members of the public, and the environment.

2801-02 OBJECTIVES

02.01 To establish general policy and priorities for the inspection of uranium mills and 11e.(2) byproduct material disposal sites.

02.02 To establish a uniform process for the inspection of uranium mills and 11e.(2) byproduct material disposal sites.

02.03 To define specific requirements for inspection of uranium mills and 11e.(2) byproduct material disposal sites.

2801-03 DEFINITIONS

03.01 11e.(2) Byproduct Material, as defined in Section 11 of the Atomic Energy Act of 1954, as amended, means tailings or waste produced by the extraction of uranium or thorium from any ore processed primarily for its source material content.

03.02 Closure, as defined in Appendix A to 10 CFR Part 40, means the activities, after operations, to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings and/or waste disposal area(s). Also, commonly referred to as decommissioning or reclamation.

03.03 Decommission, as defined in 10 CFR 40.4, means to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license. Would include remediation of the disposal area to be deeded to the Department of Energy.

03.04 Decommissioning Plan, as defined in Appendix A to Part 40, for the purposes of Criterion 6A, means the plan detailing activities to accomplish reclamation of the tailings or waste disposal area in accordance with the technical criteria of Appendix A. In practice, the Decommissioning Plan usually details the demolition and/or cleanup of the mill buildings and large equipment, tanks, etc. The plan for stabilization of the tailings and/or waste disposal areas and cleanup of contaminated soil is often referred to as the Reclamation Plan.

03.05 Operation, for a mill is the process of extracting uranium from ore. For an 11e.(2) disposal facility, it is receipt and emplacement of 11 e.(2) byproduct material.

03.06 Performance-Based License (PBL), allows the licensee to make changes to the facility without prior NRC approval if certain conditions are met. These conditions are specified in the performance-based license condition contained in the PBL. Consistent with the regulatory reduction effort initiated by the staff in 1994, the staff is currently issuing all new and renewed operating licenses as performance-based.

2801-04 PROGRAM APPLICABILITY

This program has been developed to respond to needs for inspection procedures related to construction, pre-operation, operations, and reclamation/closure for sites licensed by NRC. Where 11e.(2) byproduct material disposal sites are operating under Agreement State regulation, it is expected that responsibility for regulation and inspection activities at those sites will continue to reside with the Agreement States. It is noted that existing inspection procedures from other NRC programs can be applied, in full or in part, to many aspects of uranium mill and 11e.(2) byproduct material disposal site inspections, and that additional inspection procedures specific to disposal technology, and on-site activity can be developed and employed incrementally, as needed. Tables 1 and 2 provide a listing of procedures that are currently available and include comments concerning their applicability. Minimum and normal frequencies of inspection are listed; adoption of the minimum frequency of inspection should be tailored to both the level of site activity and to the performance of the licensee.

2801-05 PROGRAM DESCRIPTION

05.01 General. The inspection program for sites specifically licensed for 11e.(2) byproduct material disposal, and for uranium mills has been divided into three parts. The parts are designed to be responsive to the various inspection needs during the different phases of facility life: construction/pre-operations, operations, and reclamation/closure. Each phase of the inspection program varies with respect to applicable inspection procedures, inspection frequency, and degree to which a given procedure may be applied. The inspection programs for each phase are discussed in narrative form in Section 2801-08. Tables 1 and 2 present information for the pre-operations, operations, and closure phases.

This chapter identifies requirements for the inspection of the health, safety, and environmental aspects of licensee activities. The inspector should be completely familiar with the current regulatory requirements and commitments associated with the license. These include the comparable parts of title 10, U.S. Code of Federal Regulations, the license application, applicable guides, and other codes to which licensees may commit by reference. In the case that Nuclear Regulatory Commission guidance documents are updated after a license or amendment is issued, the licensee is generally only committed to follow the original guidance. Thus, the particular revision of the guidance to which the licensee has been committed is of importance.

The scope of inspection procedures (IPs), taken as a whole, is not intended to be limited to only those elements discussed in the procedures. The descriptions and examples contained in the procedures are provided primarily for illustrative purposes, as examples of things that should be examined. Examination of other safety-significant activities not expressed or implied in a procedure is left to the

inspector's judgment, in consideration of the relative degree of safety risk posed by the subject activity.

The environmental aspects of the activities relate to those license conditions that have been placed on the operation by the Nuclear Regulatory Commission as a result of reviews conducted under the authority of the National Environmental Policy Act. Environmental inspections would be conducted at the same time as health and safety inspections.

05.02 Adjustments. The program provides regional offices the flexibility to adjust the frequencies of inspections, within the various program areas, based on an evaluation of the inspection findings and enforcement experience with a particular licensee. Alternate frequencies of inspection for various procedures are specified in Tables 1 and 2. The lower frequency specified is the minimum frequency to which the inspection may be reduced by the regional office. The higher frequency of inspection specified for the procedure shall be the normal inspection frequency for the program. There is no maximum frequency expressed in Tables 1 and 2. It is expected that any level of effort (i.e., frequency of inspection) above that specified as the normal frequency would be established at a level commensurate with whatever is needed to resolve identified problems and their importance to safety.

05.03 Performance-Based License. At sites operating under a PBL, the inspector should ensure that changes authorized under the PBL do not erode the basis for NRC's licensing decision. In evaluating the changes made to the facility, inspectors should recognize that the reviews conducted by the licensee's evaluation panel are not reviews of safety nor environmental acceptability. Rather, the evaluation panel reviews under the PBL are a determination of whether the proposed changes require prior NRC review. Licensees are obligated to ensure that any change considered to the facility should be safe and environmentally acceptable. Then the evaluation panel is responsible for determining if the proposed changes need to be submitted to NRC. There will be circumstances where the licensee finds that the proposed changes are acceptable; however, the change may still require an NRC review.

As a general set of guidelines, those changes that will require NRC review include changes to:

1) Those things described in the application or subsequent submittals that would reduce the safety basis of the facility;

2) Procedures conditioned in the license or outlined, summarized, or included in the application; and

3) Things specifically conditioned in the license.

Additional guidance on the inspection of PBL activities undertaken by licensees can be found in IP 37001, "10 CFR 50.59 Safety Evaluation Program." Although this IP is applicable to 10 CFR Part 50 licenses, the basic philosophy and inspection process can be adopted to PBLs since the PBL concept was derived from 10 CFR 50.59.

2801-06 REVIEW OF EVENTS

All inspections should include, as appropriate, a review of licensee reportable and non-reportable events that involve contamination, releases, equipment malfunctions, or other similar events that have generic significance. The review should cover corrective actions taken by the licensee and follow-up actions taken to prevent recurrence. In the case of reports received by NRC involving radiological health and safety, the region is responsible for determining the seriousness of the reported incident and whether an immediate reactive inspection is necessary. When such reports involve programmatic areas normally addressed by Headquarters programs, the region shall confer with Headquarters, to jointly determine what response, if any, is required, including whether the NRC response should include personnel from the Headquarters.

Non-reportable events are those determined by the licensee to fall outside criteria requiring them to be reported to NRC. Although, these events are not reported formally to NRC, licensees occasionally may contact regional staff informally to describe the event and explain it is not required to be reported. Still, licensees are often required, through license conditions or commitments, to maintain records of non-reportable events onsite. Non-reportable events should be examined during inspections, to determine appropriate corrective actions or follow-up to preclude recurrence: these events may involve safety issues that should be followed up by the Occupational Safety and Health Administration, Mine Safety and Health Administration, and existing or potential operational difficulties not otherwise reportable, such as biointrusion in disposal units, erosion or sloughing of trench walls, or uncontrolled wind erosion. Additional guidance on non-reportable events is contained in individual inspection procedures.

2801-07 INDEPENDENT INSPECTION EFFORT

Each inspector should spend some onsite inspection time performing independent inspection effort. The amount of time spent should be commensurate with the level of risk, the complexity of the facility, and the degree to which inspection resources have already been committed to significant safety and environmental issues that have already been identified in the facility. This effort may include more in-depth

inspection in selected technical areas than that normally called for by the formal procedures. The major objective of this effort should be to gain increased understanding of potential safety and environmental hazards of particular activities of interest, such as those that may have been involved in a series of recent non-reportable events.

Comparison of the findings from this type of effort with the licensee's findings may uncover unresolved safety and environmental questions, improper maintenance practices, and other problems that may not be discovered through other means. Discovered hazards outside the scope of Nuclear Regulatory Commission IPs or Nuclear Regulatory Commission regulatory authority should be conveyed to the licensee at the exit interview (as set forth in IP 88002), described to regional management during debriefing, and included in the formal inspection report. In cases where regulatory jurisdiction for the observed potential hazard is clear, the finding shall be reported to the responsible agency for action (i.e., State, Mine Safety and Health Administration, Environmental Protection Agency, etc.). In all cases where the finding involves a potential effect on radiological health and safety, the finding shall be followed during subsequent inspections until the licensee has addressed the concern. However, special follow-up inspections solely on the basis of Mine Safety and Health Administration issues are not required unless the potential hazard also directly involves radiological health or safety.

2801-08 RANDOM SELECTION AND EXAMINATION OF RECORDS

Many of the inspection procedures normally require the inspector to select certain types of records at random for closer examination. However, random selection is not always required. The inspector may seek out certain records of interest when so inclined.

Random selection is a technique that recognizes the fact that the Nuclear Regulatory Commission does not have the resources to inspect every detail of plant. The Nuclear Regulatory Commission inspection program is predicated on the fact that the licensee is ultimately responsible for the safety of the licensed facility. Random selection, where specified in a procedure, allows the inspector to sample specific aspects of the licensee's safety and environmental program to be studied at a level of detail that would be impractical if exercised uniformly across the entire safety program. When random selection in a procedure is specified, the inspector should select records corresponding to activities that relate to the Nuclear Regulatory Commission's regulatory role, such as effluent monitoring records or ground-water restoration records. Also included should be records required to be retained for later decommissioning.

To reasonably verify that activities are conducted safely and in an environmentally acceptable manner, the inspector also should randomly select personnel for interviews. The extent and depth to which random selections or examinations are

needed are left to the inspector's judgment, depending on how satisfied the inspector is that operational and safety safeguards procedures are being followed uniformly.

2801-09 REGIONAL RESPONSIBILITY FOR LICENSEES

The responsibility for inspection resides with the regional office in which the licensee operation is located. For efficiency in resource use, the regional office may request another regional office or Headquarters to assist in the conduct of inspections when specialized technical expertise is needed and is not available within the responsible region. In some cases, a region may wish to transfer all or part of the inspection responsibility to another region or to Headquarters. These arrangements may be made with mutual agreement between the offices involved. If a permanent transfer of total inspection responsibility is involved, the affected regional offices should ensure that the appropriate changes are made to the computerized license data file by informing the Office of Nuclear Material Safety and Safeguards of the change in inspection responsibility for the license and requesting a change in the file. The regional office assuming inspection responsibility will be credited with the caseload in budgeting and allocating resources.

2801-10 INSPECTION DURING VARIOUS PHASES OF FACILITY LIFE

10.01 Part I - Inspection During the Construction and Pre-Operational Phase

a. Purpose. The purpose of this instruction is to provide guidance for planning and conducting inspections during the construction/pre-operations phase of facility life. Activities encompassed during the construc-tion/pre-operations phase of a uranium mill or disposal site include disposal trench construction: liner placement: observation and verification of placement and compaction of cover materials: equipment use: fire protection program (equipment and training procedures):, and compliance with applicable construction specifications requirements in accordance with applicable management controls and quality assurance procedures. Activities encompassed during start-up of a mill that has been on stand-by, would include equipment operation/function and safety.

b. Implementation. This inspection program begins on issuance of the license, or license amendment to restart the mill, and continues until the site begins active receipt and disposal of waste, or processing of ore at a mill. Situations may arise in which inspection requirements specified for other phases may apply concurrently with those specified here for the pre-operational phase. For example, certain

requirements contained under Parts I and II may apply in the construction, pre-operational checks, and start-up of a major modification to the site.

The uranium mill or 11e.(2) byproduct material disposal site pre-operational inspection program is defined by selection from among the list of procedures in Table 1. The areas covered during an inspection need not be limited only to those elements discussed in the procedures, but may need to include examination of other activities not expressly delineated or covered in existing procedures. In such cases, the inspector must exercise good professional judgment in modifying the inspection and in identifying to the program office the possible need for development of supplemental guidance. Conformance with the principles of reducing radiation exposure to as low as is reasonably achievable (ALARA) should be a principal concern at all times.

For the normal inspection frequency, each procedure should be executed for each specific frequency. In practice, part or all of the procedure element may need to be examined during each inspection visit.

During inspections, emphasis should be placed on physical examinations, observation of conduct of operations, independent measurements, and personnel interviews. Attention should be directed toward the availability of written procedures, the degree to which they are being followed, and the state of training of on-site personnel. Effort should be concentrated on areas of perceived concern (highest safety risk) and site activities performed since the last inspection.

Review of records should involve only a sampling of those records important to safety of personnel and the general public. For example, if the organizational structure has not changed with respect to personnel and assigned functions and responsibilities, the inspector should not pursue the subject of organization in any detail, unless there is reason to believe that such is not the case. Discretion in such areas is left to the inspector's judgement.

c. Regulatory Considerations. The inspector should be familiar with current license requirements; previous inspection reports; applicable codes, standards and guides; and the following regulations:

10 CFR Part 19, "Notices, Instructions, and Reports to

Workers: Inspection and Investigations."

10 CFR Part 20, "Standards for Protection against Radiation."

10 CFR Part 21, "Reporting of Defects and Noncompliance."

10 CFR Part 40, "Domestic Licensing of Source Material."

10 CFR Part 61.82, "Commission Inspection of Land Disposal Facilities (Commercial Disposal Only)."

d. Guidance for Use of Inspection Procedures during the Pre-Operational Phase. The inspection procedures indicated in Table 1 for the construction/pre-operations phase are applicable to inspections conducted at uranium mills and 11e.(2) byproduct material disposal sites during construction/pre-operations. The inspection staff can determine the applicable elements of each procedure by reviewing the procedure, the facility license, and reports of previous inspections.

10.02 Part II - Inspection during the Operations Phase

a. Purpose. The purpose of this instruction is to provide guidance for planning and conducting inspections during the operations phase of the facility. Activities encompassed during the operations phase include receipt and handling of incoming 11e.(2) byproduct material, or the processing of ore and packaging of yellowcake; emplacement of the 11e.(2) byproduct material for disposal; radiation safety and environmental monitoring activities; and records management.

b. Implementation. This inspection program begins on issuance of the facility license, or a license amendment to allow a uranium mill on stand-by to restart, and continues until the facility ceases active receipt of materials and/or disposal of waste. Situations may arise in which inspection requirements specified for other phases may apply concurrently with those specified here for the operations phase. For example, certain requirements contained under Parts I and III may apply in the operations, or start-up of a facility.

The uranium mill or 11e.(2) byproduct material disposal site operations inspection program is defined by selection from among the list of procedures in Table 2. The areas covered during an inspection need not be limited only to those elements discussed in the procedures, but may need to include examination of other activities not expressly delineated or covered in existing procedures. In such cases, the inspector must exercise good professional judgment in modifying the inspection and in identifying to the program office the possible need for development of supplemental guidance. Conformance with the principles of ALARA should be a principal concern at all times.

For the normal inspection frequency; each procedure should be executed for each specific frequency. In practice, part or all of the procedure element may need to be examined during each inspection visit. Emphasis should be placed on physical examinations, observation of conduct of operations, independent measurements, and personnel interviews. Attention should be directed toward the availability of written procedures, the degree to which they are being followed, and the state of training of on-site personnel. Effort should be concentrated on areas of perceived concern (highest safety risk) and licensee activities conducted since the last inspection.

Review of records should otherwise involve only a sampling of those records important to safety of personnel and the general public. For example, if the organizational structure has not changed with respect to personnel and assigned functions and responsibilities, the inspector should not pursue the subject of organization in any detail, unless there is reason to believe that such is not the case. Discretion in such areas is left to the inspector's judgment.

c. Regulatory Considerations. The inspector should be familiar with current license requirements; previous inspection reports; applicable codes, standards and guides; and the following regulations:

10 CFR Part 19, "Notices, Instructions, and Reports to Workers:

Inspection and Investigations."

10 CFR Part 20, "Standards for Protection against Radiation."

10 CFR Part 21, "Reporting of Defects and Noncompliance."

10 CFR Part 40, "Domestic Licensing of Source Material."

10 CFR Part 61.80, "Maintenance of Records, Reports, and Transfers."

10 CFR Part 61.82, "Commission Inspection of Land Disposal Facilities

(Commercial Disposal Only)

d. Guidance for Use of Inspection Procedures During Operations. The inspection procedures indicated in Table 2 for the Operations Phase are applicable to inspections conducted at uranium mills and 11e.(2) byproduct material disposal sites, including mills authorized for disposal of in-situ leach facility waste and other 11e.(2) byproduct material. The inspection staff can determine the applicable elements of each procedure by reviewing the procedure, the facility license, and reports of previous inspections. Inspectors should also refer to applicable portions of Regulatory Guides 4.14, 8.22, and 8.30, for details.

10.03 Part III - Inspection During the Reclamation/Closure Phase.

a. Purpose. The purpose of this instruction is to provide guidance for planning and conducting inspections during the period of reclamation/closure of a uranium mill site or 11e.(2) byproduct material disposal site. In some cases, as specifically allowed or required by license condition, some closure activities may occur for some parts of a facility during the operations phase. The purpose of the inspection is to verify, by field observations and review of licensee records, that decontamination of soil, sediment, surface waters, and ground-water, as well as reclamation of the disposal cell, are being performed in accordance with NRC-approved plans.

b. Implementation. This program is initiated when the licensee begins implementation of any portion of the approved reclamation/decommissioning plan. The foundation for planning and scheduling inspections will thus be the licensee's progress in implementing the reclamation plan (construction schedule). The criteria for inspections will be license conditions and applicable regulations, some of which will directly address reclamation activities. In many cases, portions of the reclamation plan may be implemented for part of a site while active operations continue elsewhere on site. In these cases, the appropriate portions of this program should be implemented in conjunction with the operations inspection program. The reclamation plan itself, as amended during site operation and approved by NRC, should be reviewed by the regional office to determine if procedural or scheduling modifications are necessary to enable planning of an efficient inspection program. The inspection program continues in effect until the licensee has implemented all elements of the reclamation plan, the license is terminated, and the title to the land is transferred to the U.S. Department of Energy for long-term surveillance and maintenance.

The 11e.(2) byproduct material disposal site, or uranium mill reclamation and decommissioning inspection program is also defined by selection from among the list of procedures in Table 2. The areas covered during an inspection need not be limited only to those elements discussed in the procedures, but may need to include examination of other activities not expressly delineated or covered in existing procedures. In such cases, the inspector must exercise good professional judgment in modifying the inspection and in identifying to the program office the possible need for development of supplemental guidance. Conformance with the principles of ALARA should be a principal concern at all times.

For inspections during site remediation/closure (includes licensee performing cleanup verification measurements), each procedure should be executed for each specific frequency. In practice, part or all of the procedure element may need to be examined during each inspection visit. Emphasis should be placed on physical examinations, observation of conduct of operations, limited independent measurements (e.g., split samples), and personnel interviews. Attention should be directed toward the availability of the licensee's written procedures, the degree to which they are being followed, and the state of training of on-site personnel. Effort should be concentrated on areas of perceived concern. Discretion in such areas is left to the inspector's judgment in consultation with Headquarters staff (project manager, technical reviewers).

A confirmatory survey may be performed as an audit of the licensee's final survey results, to independently confirm that the report is accurate and representative of site conditions, but is only necessary if there is significant doubt regarding the licensee's final survey results. A confirmatory survey will be performed if one or more of the following apply to decommissioning of the site: 1) repeated violations, with the inclusion of a "management paragraph"; 2) issuance of an order; 3) failure to take short-term corrective measures; 4) event requiring a reactive inspection; 5) limited financial and technical viability of the licensee; and 6) significant problems identified with the reclamation plan or final survey data.

c. Regulatory Considerations. The inspector should be especially familiar with current license requirements; previous inspection reports; applicable codes, standards and guides; and the following regulations:

10 CFR Part 20, "Standards for Protection against Radiation."

10 CFR Part 40, "Domestic Licensing of Source Material."

10 CFR Part 61.82, "Commission Inspection of Land Disposal

Facilities (Commercial Disposal Only)."

d. Guidance for Use of Inspection Procedures During Closure The inspection procedures indicated in Table 2 are applicable, as noted, to inspections conducted at 11e.(2) byproduct material disposal sites, or uranium mills during closure. The most applicable procedure is under development and will be entitled, "Decommissioning Inspection Procedure for Uranium Mill Sites." The inspection staff can determine the applicable elements of each procedure by reviewing the procedure, the facility license, and the licensee's closure (reclamation) plan.

END

Attachments:

Table 1, Inspection Procedures Applicable to Pre-Operational Inspection of a Uranium Mill or 11e.(2) Byproduct Material Disposal Site

Table 2, Inspection Procedures Applicable to Inspection of a Uranium Mill or 11e.(2) Byproduct Material Disposal Site during Operations and

Closure

TABLE 1 - INSPECTION PROCEDURES APPLICABLE TO PRE-OPERATIONAL INSPECTION OF A URANIUM MILL OR 11e (2) BYPRODUCT MATERIAL DISPOSAL SITE

Procedure Number	Procedure Title	Inspection Frequency Minimum Normal	Applicability of Procedure to the Inspection
30703	Management Entrance/Exit Interview	Each Each Inspection Inspection	The general principles of the procedure are applicable.
36100	10 CFR Part 21 Inspection at Nuclear Power Reactors	As As Necessary Necessary	Inspectors should be sensitive to the underlying principle driving this procedure.
37001	10 CFR 50.59 Safety Evaluation Program	As As Necessary Necessary	As applicable to implementation of performance-based license (PBL) since the PBL concept was derived from 10 CFR 50.59.
88001	Construction Review	Annual Key Construction Milestones	Applicable to the inspection of engineering and construction aspects.
88005	Management Organization and Construction	Annual Annual	Inspector should subscribe to the general principles established in this procedure.
88045	Environmental Protection	Annual Twice per Year	License conditions will specify offsite monitoring and sampling locations, frequencies, and applicable limits on levels and concentrations of radioactivity.
92701	Follow-up	As As Necessary Necessary	Generic procedure applicable.
92702	Follow-up on Violations/Deviations	As As Necessary Necessary	Generic procedure applicable.
92703	Confirmatory Action Letters	As As Necessary Necessary	Generic procedure applicable.
XXXXX	In Situ Leach (ISL) Facilities Programs	Annual Twice per Year	Applicable to the operating aspects generic to uranium mills and in-situ leach facilities.

TABLE 2 - INSPECTION PROCEDURES APPLICABLE TO INSPECTION OF A URANIUM MILL SITE OR 11e (2) BYPRODUCT MATERIAL DISPOSAL SITE DURING OPERATIONS AND CLOSURE

OPERATIONS PHASE CLOSURE PHASE

Procedure Number	Procedure Title	Inspection Frequency Minimum Normal	Applicability of the Procedure	Inspection Frequency Minimum Normal	Applicability of the Procedure
30703	Management Entrance/Exit Interview	Each Each Inspection Inspection	The general principles established in this procedure should be followed	As As Necessary Necessary	The general principles established in this procedure should be followed.
37001	10 CFR 50 59 Safety Evaluation Program	As As Necessary Necessary	As applicable to implementation of performance-based license (PBL) since the PBL concept was derived from 10 CFR 50.59.	As As Necessary Necessary	As applicable to implementation of performance-based license (PBL) since the PBL concept was derived from 10 CFR 50.59.
83822	Radiation Protection	Annual Twice per Year	This procedure is applicable in its entirety.	Each Each Inspection Inspection	Initially, the entire procedure should be followed to determine that the approved program is being implemented and to establish the potential for exposures. Subsequent inspections can be tailored to concentrate on identified areas of risk.
83890	Closeout Inspection and Survey	N/A N/A	N/A	Final Inspection	Use this procedure in conjunction with the new decommissioning procedure.
86740	Inspection of Transportation Activities	Annual Twice per Year	The procedure should be used to confirm compliance for yellowcake or byproduct shipments.	As As Necessary Necessary	Use the procedure only if source or byproduct material is transported off-site.
88001	On-Site Construction	Annual Twice per Year	This procedure is for the engineering and construction aspects of a disposal cell and implementation requires the assistance of Headquarters staff	As Needed As Needed	Key activities to be inspected are construction of the radon barrier and the erosion protection layer of the disposal cell.
88005	Management Organization and Controls	Annual Annual	This procedure is generally applicable. Section 03.05, Q/A Programs should be supplemented with guidance (e.g., NMSS Handbook)	Annual Annual	Inspections should determine if the approved procedures are being implemented, and if NMSS is properly involved with any changes made to a procedure.
88010	Operator Training/Retraining	Every Other Annual Year	This procedure is applicable to mill and disposal sites	Every Other Annual Year	This procedure is applicable to mill and disposal sites
88020	Operations Review	Annual Twice per Year	Some sections of this procedure apply.	Annual	See Sections 02 01b, "Inspection of Tailings Dam" and 02 02, "Housekeeping".

TABLE 2 - INSPECTION PROCEDURES APPLICABLE TO INSPECTION OF A URANIUM MILL SITE OR 11e.(2) BYPRODUCT MATERIAL DISPOSAL SITE DURING OPERATIONS AND CLOSURE

OPERATIONS PHASE CLOSURE PHASE

Procedure Number	Procedure Title	Inspection Frequency Minimum Normal	Applicability of the Procedure	Inspection Frequency Minimum Normal	Applicability of the Procedure
88025	Maintenance and Surveillance Testing	Annual Twice per Year	This procedure is for reactors, but some generally applicable points.	Annual Twice per Year	This procedure applicable only to emergency utility services and general maintenance.
88035	Radioactive Waste management	Annual Twice per Year	Sections 02 01 to 02.06 are generally applicable. The procedure needs to be updated to refer to sections of new 10 CFR Part 20.	Annual Twice per Year	Sections 02.01 to 02.07 of this procedure are generally applicable.
88045	Environmental Protection	Annual Twice per Year	This procedure is applicable in its entirety.	Annual Twice per Year	This procedure is applicable in its entirety. The potential for off-site releases will be less during closure, but must still be inspected.
88050	Emergency Preparedness	Every 2 Every 2 years years	This procedure is generally applicable. Discretion is required regarding the degree to which all requirements are inspected against as the severity of an emergency at a disposal site is much less than that at an operating mill, or other fuel cycle facilities.	Every 2 Every 2 years years	The fire protection and prevention program must be inspected. The frequency and depth of inspection depend on the type of facility and the methods of reclamation.
88104	Decommissioning Inspection Procedure for Fuel Cycle Facilities	N/A N/A	N/A	Every Every Inspection Inspection	Portions of this procedure are applicable to mill and disposal sites, but IP 88XXX is specific for uranium mill sites.
92701	Follow-up	As As Necessary Necessary	This procedure is generally applicable.	As As Necessary Necessary	This procedure is generally applicable.

TABLE 2 - INSPECTION PROCEDURES APPLICABLE TO INSPECTION OF A URANIUM MILL SITE OR 11e (2) BYPRODUCT MATERIAL DISPOSAL SITE DURING OPERATIONS AND CLOSURE

OPERATIONS PHASE CLOSURE PHASE

Procedure Number	Procedure Title	Inspection Frequency Minimum Normal	Applicability of the Procedure	Inspection Frequency Minimum Normal	Applicability of the Procedure
92702	Follow-up on Corrective Actions for Violations and Deviations	As As Necessary Necessary	This procedure is generally applicable.	As As Necessary Necessary	This procedure is generally applicable.
90703	Follow-up of Confirmatory Letters	As As Necessary Necessary	This procedure is generally applicable.	As As Necessary Necessary	This procedure is generally applicable.
93001	OSHA Interface Activities	As As Necessary Necessary	This procedure is applicable.	As As Necessary Necessary	This procedure is applicable.
XXXXX	In-Situ Leach (ISL) Facilities Program	Annual Twice per Year	Applicable to the operating aspects generic to uranium mills and in-situ leach facilities	Annual Twice per Year	Applicable to the closure aspects generic to uranium mills and in-situ leach facilities.
88XXX	Decommissioning Inspection Procedure for Uranium Mills	N/A N/A	N/A	As As Necessary Necessary	This procedure is applicable in its entirety.

NRC INSPECTION MANUAL NMSS/URB

INSPECTION PROCEDURE 87654

URANIUM MILL SITE DECOMMISSIONING INSPECTION

PROGRAM APPLICABILITY: 2801

87654-01 INSPECTION OBJECTIVES

To determine if licensed decommissioning programs are being conducted in accordance with Nuclear Regulatory Commission requirements specified in individual licenses and the regulations. To provide assurance that uranium mill site decommissioning activities are being performed appropriately to demonstrate compliance with the decommissioning regulations and guidelines, and in accordance with the approved reclamation plan. This procedure supplements Inspection Procedure (IP) 88104 and provides details specific to decommissioning uranium mill sites. This procedure is also applicable to 11e.(2) byproduct disposal sites licensed by the NRC that are not associated with a uranium mill; however, the inspector should confirm the regulatory requirements for the site as indicated in the site license.

87654-02 INSPECTION REQUIREMENTS

A determination of compliance with NRC requirements will be based on direct

observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, independent measurements of radiation conditions at the facility, and review of licensee records. The inspector should refer to Inspection Manual Chapters (IMCs) 2602, 2605, and 2801 for general policies and guidance.

The scope of the inspection of licensed activities will be commensurate with the scope and status of the licensee's decommissioning program and with previous inspection efforts. A primary decommissioning activity to be addressed is soil cleanup and cleanup verification to demonstrate compliance with Criterion 6(6) of 10 CFR Part 40, Appendix A (most mill buildings are buried in the disposal cell). However, inspection of the implementation of other radiological decommissioning requirements in Criterion 6, such as measurement of radon flux and gamma levels from the disposal cell cover, may be necessary and should be coordinated with the Headquarters health physicist. Ground-water compliance will be evaluated against Criteria 5B, 5C, 5D, 5E, 5G, and 13. Surface reclamation (includes disposal cell construction) compliance will be evaluated against Criteria 4 and 6, and is discussed in Inspection Procedure (IP) 88001. Applicable portions of 10 CFR 40.42, such as the requirements for timely decommissioning, may need to be addressed, therefore the NRC Project Manager should be consulted when the site inspection plan is being developed.

This IP should be used as a checklist when developing a site-specific decommissioning inspection plan. The decommissioning inspection plan should not duplicate the normal inspection for radiation protection and environmental monitoring, but emphasize observation of key decommissioning activities being performed. If possible, implementation of this procedure should be initiated early in the decommissioning phase, to identify any program deficiencies and to gain confidence in the licensee's performance.

02.01 Preparation. The inspector should allow adequate time to prepare for the inspection. Preparation will include reviewing documents, making travel arrangements, coordinating with appropriate staff, notifying appropriate State agencies, and selecting necessary equipment. In particular, the inspector shall identify whether any license amendments have been issued since the last inspection, or whether the licensee has informed NRC of any major program changes since the last inspection. The inspector shall also review any event files to determine if the licensee had any incidents or events since the last inspection.

02.02 Entrance Briefing. When the inspector arrives at the licensee's facility, he/she will inform an available senior management representative of the purpose and scope of the inspection.

02.03 General Overview

a. Organization. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management and the Radiation Safety Officer (RSO).

b. Scope of Program. Interview cognizant personnel to determine the scope of licensed activities, site status, staff size, etc.

c. Management Oversight. In the course of interviewing cognizant personnel, determine if management oversight is sufficient to provide the licensee staff with adequate resources and authority to administer the licensed program.

1. RSO - Determine whether the RSO has sufficient authority, and fulfills the appropriate duties commensurate with the size and scope of licensed activities.

2. Audits - Verify that audits are performed as required. Verify that the results of the audit are reviewed and addressed.

3. Determine that individuals who perform and/or supervise licensed activities are qualified and perform an appropriate level of supervision, as required by the license or regulations.

d. Decommissioning Activities. The inspection should be scheduled so that decommissioning activities can be observed, unless it is to be the final decommissioning inspection (after the Final Survey Report submitted and reviewed). Licensee decommissioning staff should be interviewed and relevant records on decommissioning activities reviewed.

e. Site Orientation Tour. A brief site tour should be made. General observations should be noted on the condition of the facility and the licensed activities being performed.

02.04 Equipment and Procedures. Review the equipment and procedures used for decommissioning the site to determine if appropriate and approved equipment and methods were followed.

02.05 Final Survey. Verify the accuracy and reliability of the licensee's final survey data by reviewing the methods used and the final survey data.

02.06 Quality Assurance/Quality Control. Verify the adequacy of the licensee's quality assurance and control program.

02.07 Data Reduction and Management. Verify the way field data is documented and processed.

02.08 Personnel Training. Verify that appropriate training and instructions were/are given. Through discussions with workers, verify that licensee personnel understand and implement the established decommissioning procedures.

02.09 Confirmatory Survey. The survey by the inspector should include gamma scans (and alpha scans if applicable) and soil analysis using methods similar to those approved for use by the licensee. The inspector's survey data is used as an indication of whether or not the licensee properly implemented the approved procedures and complied with the decommissioning criteria.

02.10 Ground Water. Verify that the ground-water monitoring and/or corrective program is being conducted (1) in compliance with Appendix A of 10 CFR 40 and (2) as required by applicable license conditions. Verify that the ponds are being monitored for leakage into the ground water as required by applicable license conditions.

02.11 Exit Meeting. When the inspection is over, there should be an exit meeting with the most senior licensee representative present, to discuss the preliminary inspection findings.

02.12 Post-Inspection Actions. After the inspection, the inspector shall summarize the findings with his/her supervisor. The inspector shall also contact Headquarters staff when any pertinent issues are raised during the inspection, when inspection findings impact on any licensing actions, or to give feedback on how the licensee has addressed recent licensing actions.

The inspection report should document what activities were observed, summarize the interviews with licensee personnel, and clearly indicate the evaluation of the licensee's decommissioning program.

03.01 Preparation. Before the inspection, the inspector should be familiar with the guidance listed in the Appendix of this IP and a review of the following should be performed.

a. Operating History. Review the history of each license to identify what types of work activities were performed, the types of buildings that existed, and the geographical location of each. Review the results of past operational radiological surveys that were used to demonstrate radiological control of the uranium mill.

b. Waste Disposal Practices and Radioactivity Releases. Verify waste disposal outside the tailings cell. Consider the potential for, or evidence of, contamination from spills, or other releases of radioactive material (such as haul routes) to compare with the soil cleanup boundary.

c. Environmental Monitoring Data. Verify operational soil sampling, airborne emissions, and ground-water monitoring data, specifically for evidence of radiological contamination. Verify effectiveness of effluent controls, particularly during drying and packaging operations, and when air was exhausted from the yellowcake stack. Determine area where airborne contamination would likely be deposited.

d. Results of Previous Surveys. Verify the results of scoping, characterization, and remedial action support (excavation control) surveys performed by the licensee. Review the results of previous surveys for justification of the classification of mill site areas (e.g., mill site boundaries versus windblown areas). In particular, review data for the areas adjacent to the remediation of windblown contamination.

e. Remedial Actions. Review the specific procedures that were used to decontaminate the process facilities and/or land areas. Consider the potential for incomplete remediation based on these remedial action techniques, particularly the potential for the remedial actions to produce areas of localized contamination within verification grids that were not represented in the gamma scan average value. Determine if the licensee has identified the need to remediate radionuclides other than radium-226 (Ra-226).(e.g., beneath acidic raffinate ponds) where thorium-230 (Th-230) could migrate farther than Ra-226 or where uranium ore residue or yellowcake contamination could be located.

f. Guidelines Established. Review the guidelines that the licensee is using for indoor and outdoor areas and verify how the stated guidelines are being implemented:(e.g., use of surrogate measurements, presence of multiple contaminants, averaging conditions, and hot spots).

g. Records. Review the site's previous inspection history, license conditions, and licensee's submittals concerning decommissioning, and the Technical Evaluation Reviews for the related amendments, to be aware of follow-up inspection items, commitments made by the licensee, and assumptions or conclusions, made by licensing staff, related to decommissioning.

h. Background Reference Areas. Identify the value that NRC licensing staff approved as the site Ra-226 soil background. Determine if any recent information might require a review of the background value to determine that its use for soil cleanup is adequate to protect long-term health and safety (e.g., soil cleanup extended into background locations).

03.02 Entrance Briefing. No specific guidance required.

03.03 General Overview. No specific guidance required.

03.04 Equipment and Procedures. The inspector shall verify the gamma surveys done by the licensee by reviewing the following:

a. Instruments. Review the basis for the selection of instruments (e.g., based on potential contaminants and their associated radiations, types of media (soil, sludge, etc.) to be verified, and detection sensitivities). Typically, sodium iodide (NaI) scintillation detectors are used for land area surveys.

b. Sensitivity. Review documentation pertaining to instrumentation sensitivity, particularly licensee statements to the effect that instrumentation will be sufficient to detect radiological contamination. The detection sensitivity should be below the appropriate guideline values. Also, verify the instrument scan sensitivity for exterior scan surveys (NUREG-1575, Section 6.4). Check the scan sensitivity in terms of the gamma soil cleanup guideline.

c. Gamma-Radium Correlation. Confirm that the licensee checked the correlation of Ra-226 concentration to gamma levels during verification, and that an acceptable correlation was obtained.

d. Methods. Verify the methods/procedures for exposure rate measurements and gamma scans, unless these were reviewed with the Reclamation Plan. If possible, observe if the measurements and scans are performed according to the procedures and good health physics practices, such that reliable data are produced.

e. Calibration. Verify the procedures for instrument calibration: (e.g., use of appropriate radionuclide calibration sources, source geometry, and appropriate consideration of environmental conditions). Check the calibration date of survey meters.

f. Check-out. Review the operational check-out of survey instrumentation. Verify frequency of operational checks (both to calibration source and background) and if instrument response fell within predetermined acceptance criteria.

The inspector should verify the surface scans of buildings and equipment by reviewing the following:

a. Instruments. Review the basis for the selection of instruments: (e.g., based on potential contaminants and their associated radiations, surface types to be verified, and detection sensitivities). Typically, Geiger Muller, gas proportional, or zinc sulfide detectors are used for building surface contamination surveys. Verify the energy dependence of the measurement instrument and determine if the licensee has appropriately addressed this issue. Remember that beta detectors are more sensitive to for "old" yellowcake than alpha detectors.

b. Sensitivity. Review documentation pertaining to instrumentation sensitivity, particularly licensee statements to the effect that instrumentation will be sufficient to detect radiological contamination. The detection sensitivity should be below the appropriate guideline values. Verify the instrument scan sensitivity for both the interior and exterior scan surveys of building surfaces (NUREG-1575, Section 6.4).

c. Equations. Review the licensee's minimum detectable contamination equation for direct measurements on building surfaces and the conversion of counts to activity (should use the 4 efficiency factor).

d. Calibration. Verify the procedures for instrument calibration, e.g., appropriate radionuclide calibration sources, source geometry, and appropriate consideration of surface and environmental conditions.

e. Methods. Verify the method for exposure rate measurements, unless it was part of the Reclamation Plan. Normally, measurements are done 1 meter (3 feet) from the floor and at least 1 meter (3 feet) from a corner.

f. Check-out. Review the operational check-out of survey instrumentation. Verify frequency of operational checks (both to calibration source and background) and if

instrument response fell within predetermined acceptance criteria.

03.05 Final Survey. The inspector should verify the level of survey coverage for structures and land areas, based on the area classification (e.g., mill site or windblown area; affected or unaffected). The inspector should review the licensee's procedures for performing surface activity measurements and scans on building surfaces, for performing soil sampling, and ground-surface scanning. When possible, the inspector should observe implementation of the procedures to determine if the procedure is followed and performed in a manner reflecting good health physics practices. In particular, review the following:

a. Measurements. Determine whether the type, location, and number of measurements and/or samples per area are sufficient to provide a good representation of the radiological contamination. NUREG/CR-5849 should be consulted for general guidance.

b. Boundaries. Ensure that the boundaries of the windblown areas have been appropriately determined (review gamma data and perform spot-check gamma scans), and that any potential subsurface radioactive material deposits have been addressed.

c. Follow-up. Determine the use of investigation levels for measurements results and if the licensee performed appropriate follow-up actions. For example, soil samples should be collected if the NaI scintillation detector readings exceed a specified investigation level.

d. Sample and Analytical Procedures. Verify the licensee's sample collection and preparation techniques and equipment; (e.g., mixing, drying, geometries used for gamma spectrometry on soil samples, ingrowth period for Ra-226 progeny, etc.). Review the licensee's analytical procedures for radiological analyses, particularly the analysis of soil samples by gamma spectrometry. If a contract laboratory was used, those procedures should be available for review, including sample chain-of-custody procedures.

e. Meters. Review the protocol the licensee uses to interpret the gamma spectrometry results, particularly the radionuclide peaks used to identify various contaminants. Check for drift checks, energy calibration, control charts, duplicate sample counts, split samples with outside laboratory, etc. Determine whether the survey meters and gamma spectrometer are maintained and operated in accordance with the manufacturer's recommendations and good health physics practices.

f. Replaced Data. Review survey results for those areas where additional investigations have been conducted. If initial survey data have been replaced or supplemented as a result of the investigation, ensure that the replacement data are annotated in the final report. The annotation is intended to alert the reviewer that

the initial data have been replaced.

g. Survey data. Select a portion of completed survey data and review data for compliance with procedures and final survey plan. Review the documentation for scan surveys to determine how the licensee identified and investigated any elevated readings during the scan survey. Review survey results for specific processing areas that have been remediated, including buried raffinate lines, evaporation ponds, etc. Determine if results demonstrate compliance with guidelines and whether any modifications to the general survey approach were necessary.

03.06 Quality Assurance/Quality Control

a. Laboratory. Review the licensee's on-site laboratory and/or licensee's contracted off-site laboratory quality assurance/quality control procedures, including duplicates, blanks, and matrix spikes. Determine the frequency of analysis for each of the quality control (QC) checks. Determine whether the laboratory participates in cross-check of performance evaluation programs, such as those offered by the Environmental Monitoring Laboratory and the U.S. Environmental Protection Agency.

b. Final Data. Review the final survey report data and discuss with the Headquarters health physicists, to ensure that the items listed below are adequately addressed either in the report or in the licensee's records:

1. QC sampling and direct measurements, along with associated acceptance criteria and corrective actions.

2. Verification of survey measurement data (i.e., data quality assessment to determine adequacy of the collected data, for the intended use). Examples of data quality assessment include verification that the collected data are applicable to the statistical model used to reduce the data, and other data quality indicators, including completeness, comparability, representativeness, precision, and accuracy.

3. Testing of computer calculations by manual calculation.

03.07 Data Reduction and Management

a. Program Review. Perform a program review to determine if the licensee has set up a data reduction process with criteria stated in procedures, and if the licensee's computer software has data reduction features in the analysis, counting, and data

reporting.

b. Spot Check. Select a completed survey data package, the data reduction procedure, and verify implementation by performing the data reduction process under the direction of the licensee.

1. Trace the path of data from their generation in the field or laboratory, to their final use.

2. Review any checklist forms used for preventing loss of data during data reduction.

3. Ensure that data reduction analysis information are reflected in the final survey results.

03.08 Personnel Training. Review the qualifications and training for survey technicians and other project personnel. If possible, question technicians about their knowledge of procedures and the frequency or detail of their training.

03.09 Confirmatory Survey. Verify the need for a confirmatory survey based on the criteria in IMC 2801. A confirmatory survey by the inspector and/or NRC contractor should only be necessary if there is significant doubt regarding the licensee's final survey results. The extent of the survey (e.g., gamma survey and soil analysis) should be determined with input from the Headquarters health physicist who reviewed the Final Survey Report. Confirmatory analysis of archived soil samples may be included.

03.10 Ground Water. Verify that ground-water quality data were collected at the correct locations and frequency, as required by the license (NRC-approved radiological environmental monitoring program), were analyzed for the right constituents, and were verified to make a determination against established detection or compliance standards, as appropriate. Confirm that if ground-water quality data indicated detection or compliance standards (including compliance standards set by Alternative Concentration Limits) were exceeded, that the licensee appropriately notified NRC and took appropriate sampling and, if necessary, corrective actions. Visually verify that compliance wells are correctly located with respect to the most recent NRC-approved locations. If applicable, verify that ground-water corrective action programs were conducted in a timely manner. Also, verify that wells and boreholes that must be sealed under the approved reclamation plan, were correctly sealed and abandoned.

Visually verify that: (1) there are no failures or breaks in impoundment embankments, (2) that there are no obvious tears in impoundment liners, and (3) that there are no springs and seeps around impoundment embankments. If applicable, visually verify that the impoundment leak-detection and impoundment water-level monitoring systems are in place and operational. Verify that the licensee is conducting the appropriate level of visual inspections of impoundment integrity. If applicable, verify that the impoundment leak detection system is being monitored at an appropriate frequency and for the correct indicator parameters. Verify that appropriate monitoring, cleanup, corrective actions, and regulatory notifications were taken when impoundment fluids were found in the impoundment ground-water leak-detection system.

03.11 Exit Meeting. When the inspection is over, there should be an exit meeting with the most senior licensee representative present at the facility (see IP 30703 for details). If a senior management representative is unavailable for the exit meeting, the inspector may hold a preliminary exit meeting with appropriate staff on site.

03.12 Post Inspection Actions. The inspector will review his or her inspection findings with his or her supervisor and discuss violations, items of concern, and unresolved items in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

The inspector should also discuss inspection findings with the appropriate Headquarters staff to inform the staff about how the licensee has addressed (or failed to address) special license amendments or recent licensing actions. Licensing information requested by the licensee should also be discussed with the Headquarters staff.

Inspectors should be aware that NRC has entered into several memoranda of understanding, with other Federal agencies, that outline agreements on items such as exchange of information and evidence in criminal proceedings. The inspector should ensure that the exchange of information relevant to inspection activities is made in accordance with the appropriate memorandum of understanding.

87654-05 REFERENCES

The following NRC IMCs and related IPs should be used for guidance, in part, for the

decommissioning inspection:

- IMC 1230 "Quality Assurance Program for Radiological Confirmatory Measurements"
- IMC 2602 "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"
- IMC 2605 "Decommissioning Procedures for Fuel Cycle and Materials Licensees"
- IMC 2801 "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program" [revised August 1997]
- IP 30703 "Management Entrance/Exit Interview"
- IP 88001 "Construction Review"
- IP 88104 "Decommissioning Inspection Procedure for Fuel Cycle Facilities"

Applicable portions of the following NRC documents should be used for guidance:

- Draft BTP "Site Characterization for Decommissioning" November 1994, NRC, NMSS/DWM
- NUREG-1505 "A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys" Draft, August 1995 (only Section 4)
- NUREG-1506 "Measurement Methods for Radiological Surveys in Support of New Decommissioning Criteria" Draft, August 1995 (Sections 2 to 4)
- NUREG-1507 "Minimum Detectable Concentrations with Typical Radiation Survey

Instruments for Various Contaminants and Field Conditions" Draft, August 1995

- NUREG-1575 "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)" Draft, December 1996 (particularly Sections 5.5 and 6.0)

- NUREG/CR-5849 "Manual for Conducting Radiological Surveys in Support of License Termination" Draft 1992

- NUREG/BR-0241 "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees" March 1997

END

U.S. NUCLEAR REGULATORY COMMISSION

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REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 3.11.1

OPERATIONAL INSPECTION AND SURVEILLANCE OF EMBANKMENT RETENTION SYSTEMS FOR URANIUM MILL TAILINGS

A. INTRODUCTION

Each licensee who processes or refines uranium ores in a milling operation is required by §20.1 of 10 CFR Part 20, "Standards for Protection Against Radiation," to make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable, taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety. In addition, 40 CFR Part 190, "Environmental Radiation Standards for Nuclear Power Operations," requires that the maximum annual radiation dose to individual members of the public resulting from fuel cycle operations be limited to 25 millirems to the whole body and to all organs except the thyroid, which must be limited to 75 millirems. Liquid and solid wastes (tailings) generated by the uranium milling operation contain radioactive materials in excess of the discharge limits and are generally confined by an embankment retention system.

Regulatory Guide 3.11, "Design, Construction, and Inspection of Embankment Retention Systems for Uranium Mills," describes a general basis for inspection of an embankment retention system. This guide, a supplement to Regulatory Guide 3.11, describes in greater detail a basis acceptable to the NRC staff for developing an appropriate inservice inspection and surveillance program for earth and rockfill embankments used to retain uranium mill tailings. It results from review and action on a number of specific cases and reflects the latest general approaches to the problem. The NRC staff will review any alternative methods to determine their acceptability.

B. DISCUSSION

The milling of uranium ores results in the production of large volumes of liquid and solid wastes (tailings). These tailings are usually stored behind man-made retaining structures, following the practice of the non-uranium mining industry. Unlike most non-uranium mine tailings, uranium mill tailings contain concentrations of radioactive materials in excess of the allowable discharge limits (Ref. 1). Furthermore, the most significant radioactive element in the tailings is radium-226, which has a half-life of about 1600 years (Ref. 2). Therefore, it is necessary to confine those tailings to prevent or control their release to the environment not only during the operating life of the mill but also for generations after milling operation has ceased. The embankment, foundation, and abutments need to be stable to prevent the uncontrolled release of the retained water or semifluid tailings. Seepage from the tailing pond, which contains dissolved radium and other toxic substances (Ref. 2), needs to be controlled under normal and severe operating conditions to prevent the possibility of unacceptable contamination of the groundwater or nearby streams. Wind and water erosion of the tailings needs to be prevented during and after the milling operation.

Therefore, the design and construction of these facilities require a high degree of professional engineering performance. The foundation of the dam should be stable and should be capable of carrying the weight of the structure. The dam should be safe under the application of external forces such as those resulting from earthquakes. The reservoir area should be water retentive and free of the possibilities of dangerous slides. Dams and

associated facilities should be maintained in good working condition throughout their operating lives. Operation and surveillance through the years should be conducted in such a manner that any changes in their structural, hydraulic, and foundation conditions can be detected promptly and corrections made.

Statistics of water retention dam failures, based on the sum of operation years of a regional group of dams (Ref. 3), show a frequency of one failure every 1500 to 1800 dam-years. Statistics of uranium mill tailing retention dam failures show a frequency of one failure every 40 dam-years (Ref. 4).

Causes of latent danger inherent in such works arise from site conditions, hydrologic and hydraulic features, types and qualities of the structures, operation and maintenance, and influence of the environment (Refs. 3, 5, 6, and 7). Of these causes, the majority lie within the boundaries of modern technology and can be avoided. Most failures have resulted from gradually worsening defects (due to design, construction, operation, or lack of maintenance) that were either undiscovered or misjudged. Table 1 lists the reported tailing accidents from 1959 through 1977.

The design and construction of tailing retention structures have, in the past, been based largely on mining experience, with little use of design concepts. These empirical approaches have resulted in various mining dam mishaps and failures (Refs. 8 and 9). The latest advances in geotechnical engineering, together with engineering experience and knowledge available in the field of water storage dams, can be used in the design and construction of tailing retention dams. However, the retention systems may not always perform as expected, construction may be defective, and foundations may need further treatment after a period of operation. To detect such behavior deviations, regular surveillance is essential.

The weakening of a dam or its foundation may become apparent only after many years of safe operation. Painstaking monitoring and analysis of performance data are necessary to ensure detection of adverse conditions. Each structure, as well as each site, has its own characteristics and its own susceptibilities to problems, and the surveillance program should be tailored to account for these.

Thorough physical examination is an essential part of the surveillance program. The optimal frequency of inspections depends on the size and condition of the facilities, the character of the foundation, the regional geological setting, and the consequences of failure in jeopardizing human life and inflicting property damage.

Before the start of tailing disposal, it is important that records of piezometer levels (including seasonal fluctuations, groundwater quality, ground elevations, and background radioactivities at the site) be compiled so that comparison can be made with the effects of the impoundment. As soon as the tailing disposal begins, the inspection and maintenance program for structures and operating equipment needs to be initiated. This program includes regular patrol of the dam and its abutments, observations and estimates of seepage flows, piezometric levels related to pond levels, structural and foundation movements, sampling of groundwater, and examination of slurry transport and decant pipelines. Attention also needs to be focused on inspection and data collection during relatively rapid changes in reservoir water surface elevations. Emergency discharge and diversion channels need to be examined for any conditions that may impose constraints on their function.

The operation of the slurry transport pipelines seems to be relatively simple, but the frequent ruptures of the pipelines (Ref. 10) indicate that close monitoring needs to be performed during operation. A certain degree of segregation occurs, with the coarse sand fraction of the tailings tending to settle at the bottom portion of the pipe. On relatively steep downslopes, the coarse sand fraction cascades down and, in the process, abrades the pipe wall. When air is entrained in the pipeline, the pulp velocity increases as a result of the reduced cross-sectional area of the pulp flow and results in relatively fast wear on the pipe wall. Regular pipe-wall-thickness determinations will enable various remedial measures to be adopted to alleviate the situation.

Inspection personnel need to be carefully selected. It is important that they be practical, dedicated diagnosticians who examine thoroughly every clue during their scrutiny of the behavior of these facilities. They need to be trained to be able to recognize and assess signs of possible distress or abnormality and to recommend appropriate mitigating measures.

C. REGULATORY POSITION

This guide applies to those systems or portions of systems whose failure could cause releases of radiological effluents in excess of the limits given in 10 CFR Part 20. Inservice inspection and surveillance should be performed at regular intervals to check the condition of the retention systems and associated facilities and to evaluate their structural safety and operational adequacy. A detailed, systematic inspection and surveillance program should consist of, but not necessarily be limited to, the following:

1. Engineering Data Compilation

Engineering data[1] related to the design, construction, and operation of the tailing retention systems should be collected and, to the extent practicable, included in the initial inspection report. These data should include the following items, where available and appropriate:

a. General Project Data

(1) Regional vicinity map showing the project location and the upstream and downstream drainage areas.

(2) As-built drawings and photographs of important project features, including details of decant systems and typical installation of instrumentation (e.g., sectional views and material zoning and foundation stratification, final top and bottom elevation, gradation and properties of materials placed in installation).

b. Hydrologic and Hydraulic Data

(1) Drainage area and basin characteristics.

(2) Storage for tailings and surcharge capacities for floods and rate of slurry inflow.

(3) Elevation of the maximum design pool and freeboard height.

(4) Outlet facility characteristics (location, type, dimensions, and elevation).

c. Foundation data and geological features, including boring logs, geological maps, profiles, and cross sections.

d. Properties of embankment and foundation materials, including results of laboratory tests and field tests, and assumed design material properties.

e. Pertinent construction photographs and records, including construction control tests, dewatering method and construction problems, alterations, modifications, and maintenance repairs.

f. Contingency plan, including a plan for the regulation of pond water elevation under normal conditions and during flood events or other emergency conditions.

g. Principal design assumptions and analyses, including hydrologic and hydraulic analyses, stability and stress analyses, and seepage and settlement analyses.

h. Special license conditions and discussion on how these conditions have been met.

2. Onsite Inspection Program

The onsite inspection program of the retention system should be established and conducted in a systematic manner to minimize the possibility of overlooking any significant features. A detailed checklist should be developed and followed to document the observations of each significant geotechnical, structural, and hydraulic feature, including electrical and mechanical control equipment.

The use of photographs for comparison of previous and present conditions should be included as a part of the inspection program.

The inspection should include appropriate features and items, including, but not limited to, the following:

a. Daily Inspection

(1) Decant systems should be examined for any evidence of clogging of the intake; corrosion, cracking, or crushing of decant pipes; and erosion at the discharge point. The character and quantity of water flowing into the inlet and flowing out of the discharge should be compared for evidence of cracks or open joints.

(2) Effluent from underdrain pipes should be examined for evidence of clogging, cracking, and erosion.

(3) Pond water elevations should be examined and recorded to ensure that minimum freeboard is maintained.

(4) The slurry transport system should be examined for any evidence of obstruction of the pipes or pumps due to sand clogging or ice accumulation. The pipe couplings should be examined for leakage of slurry.

(5) The retention dam should be visually inspected for signs of cracking, slumping, movement, or concentration of seepage.

b. Monthly Inspection

(1) Air particulate samples should be collected in accordance with Regulatory Guide 4.14, "Measuring, Evaluating, and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Airborne Effluents from Uranium Mills," at site boundaries near the mill tailing retention system to determine the concentration of radon-222.

(2) Slurry transport pipes should be examined using an ultrasonic device at designated critical locations (i.e., bends, slope changes) for pipe wear.

[1]Most engineering data (as presented in accordance with Section 2.5.6 of Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants") are readily available in documents filed for mill license application. A detailed reference or the original documents kept at the project site should be adequate

(3) Diversion channels should be examined for channel bank erosion, bed aggradation or degradation and siltation, obstruction to flow, undesirable vegetation, or any unusual or inadequate operational behavior.

c. Quarterly Inspection

(1) Embankment Settlement. The top of the embankment and downstream toe areas should be examined and surveyed for any evidence of unusual localized or overall settlement or depressions.

(2) Embankment Slope Conditions. Embankment slopes should be examined and surveyed for irregularities in alignment and variance from originally constructed slopes, unusual changes from original crest alignment and elevation, evidence of movement at or beyond the toe, erosions, and surface cracks that indicate movement.

(3) Seepage. The downstream face of abutments, embankment slopes and toes, embankment-structure contacts, and the downstream valley areas should be examined for evidence of existing or past seepage, springs, and wet or boggy areas.

(4) Slope Protection. The slope protection should be examined for erosion-formed gullies and wave-formed notches and benches. The adequacy of slope protection against waves and surface runoff that may occur at the site should be evaluated. The condition of vegetative or any other type protective covers should be evaluated, when pertinent.

(5) Emergency Discharge Facility. The emergency discharge facility examination should cover the structures and features, including spillway bulkheads, culverts, retaining walls, and wing walls of diversion channels, for any condition that may impose operational constraints on their functioning.

(6) Surface Water and Groundwater. Surface water and groundwater should be examined in accordance with Regulatory Guide 4.14 for radionuclides and other toxic materials.[2]

(7) Safety and Performance Instrumentation.[3] All installed instrumentation such as flow-monitoring weirs, survey monuments, settlement plates or gages, and piezometers should be examined and tested for proper functioning. The available records and readings of these instruments should be reviewed to detect any unusual performance or distress of the structure.

(8) Operation and Maintenance Features. The maintenance of operating facilities and features (such as pumps and valves) that pertain to the safety of the retention system should be examined to determine the adequacy and quality of the maintenance procedures followed in maintaining the dam and facilities in safe operating condition.

(9) Postconstruction Changes. Data should be collected on changes such as land development or large-scale tree cutting in the watershed area above the facility that have occurred since project construction and that might influence the safety of the project.

d. Special Inspection

Unscheduled inspections should be performed after the occurrence of significant earthquakes, tornadoes, floods, intense local rainfalls, or other unusual events.

3. Technical Evaluation

An evaluation of the existing conditions of the retention system should be made annually unless significant changing conditions or more frequent observation dictate earlier evaluation. The evaluation should include the assessment of the hydraulic and hydrologic capacities,[4] water quality, and structural stability based on the changes or affected parameters.

4. Inspection Report

A report should be prepared to present the results of each technical evaluation and the inspection data accumulated since the last report. These documents should be kept at the project site for reference purposes, should be available for inspection by regulatory authorities, and should be retired only on termination of the project. Any abnormal hazardous conditions observed during the inspection should be reported immediately to the NRC staff.

5. Inspection Personnel

Inspections and evaluations should be planned and conducted under the direction of experienced professional personnel also thoroughly familiar with the investigation, design, construction, and operation of these types of facilities. At each facility, this individual should ensure that all field inspectors are trained to be able to recognize and assess signs of possible distress or abnormality.

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[2]In addition to long-term quarterly monitoring, surface water and groundwater samples should be collected in accordance with Regulatory Guide 4.14 immediately at the downstream (hydraulically) locations of the tailing retention system each month for a year prior to operation to determine the concentration of natural uranium, thorium-230, radium-226, and other toxic chemicals.

[3]Immediately following installation or the discovery of any unusual condition, all instrumentation needs more frequent readings than quarterly (e.g., daily or weekly) until the patterns of the structural behaviors are stabilized

[4]If additional storage capacity is needed, NRC should be notified a year in advance.

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"Inspection, Maintenance, and Rehabilitation of Old Dams," ASCE, 1974.

TABLE 1

URANIUM MILL TAILINGS RELEASES
1959-1977

DATE	MILL AND LOCATION	TYPE OF INCIDENT	REMARKS
8/19/59	Union Carbide Green River, UT	Tailing Dike Failure	Tailings dam washed out; ca. 15,000 T sands lost to Browns Wash and Green River due to flash flood; no increase in dissolved Ra was noted in river.
8/22/60	Kerr-McGee Shiprock, NM	Raffinate Pond Dike Failure	240,000 gal of raffinate released into San Juan River; ~ 50 x 10^{-8} μCi/ml Ra-226; river samples collected several days after release showed no increase in Ra-226 background; river at Medicine Hat (100 mi downstream of plant) showed 0.36 x 10^{-9} μCi/ml Ra-226 on 8/30/60.
12/6/61	Union Carbide Maybell, CO	Tailing Dike Failure	Ca. 500 T solids released from tailings area; 200 T reached unrestricted area; no liquid reached any flowing stream. "The presence of these tailings (offsite) does not constitute a hazard, as there are no persons living in the area, nor is there any drinking water taken from surface or ground water in the near vicinity."
6/11/62	Mines Development, Inc. Edgemont, SD	Tailing Dike Failure	200 T solids washed into Cottonwood Creek and some carried 25 mi into Angostura Reservoir.
8/17/62	Atlas-Zinc Minerals Mexican Hat, UT	Slurry Pipeline Rupture	Est. 280 T solids + 240 T liquids released from broken tailings discharge line into draw 1.5 mi from San Juan River. Calculated concentration of river water would have been below 10 CFR Part 20 maximum permissible concentration.
6/16/63	Utah Construction Riverton, WY	Tailing Dike Precautionary Release	Material released by 2-ft drainage cut made to prevent cresting due to heavy rains; material released below 10 CFR Part 20 values.
11/17/66	VCA Shiprock, NM	Raffinate Line Failure	Est. 16,000 gal of liquid lost because of break in raffinate line; material spread over 1/4 acre; break occurred 1 mi from San Juan River with some small amount reaching river.
2/6/67	Atlas Corp. Moab, UT	Auxiliary Decant Line Failure	Overflow from main tailings pond overflowed aux. decant system; 440,000 gal lost; average Ra-226 concentration was 5.5 x 10^{-8} μCi/ml.
7/2/67	Climax Uranium Grand Junction, CO	Tailing Dike Failure	Dike failure of unapproved retention system released ca. 1-10 acre-ft of waste liquid into Colorado River; no indication that Ra conc. in river exceeded 10 CFR Part 20 limits.

TABLE 1 (Continued)

URANIUM MILL TAILINGS RELEASES
1959-1977

DATE	MILL AND LOCATION	TYPE OF INCIDENT	REMARKS
11/23/68	Atlas Corp. Moab, UT	Slurry Pipeline Rupture	35,000 gal of tailings slurry lost; effluent flowed down drywash and then 1/2 mile to Colorado River; riverflow sufficient to give 10,000:1 dilution; most solids settled out in drywash; measurement of river downstream of plant immediately after release and at 4-hr intervals in 24 hr following release showed U, Ra-226, Th-230 below 10 CFR Part 20 limits.
2/16/71	Petrotomics Shirley Basin, WY	Secondary Tailing Dike Failure	2,000 gal of liquid lost to unrestricted area; break in dike of effluent sump; spill frozen in place.
3/23/71	Western Nuclear Jeffrey City, WY	Tailing Line-Dike Failure	Break in sand tails slurry line caused a dike failure allowing sand tails to flow for 2 hr into natural basin adjacent to tailings site on licensee's property; fence extended to make this area restricted.
2/5/77	United Nuclear- Homestake Partners Grants, NM	Slurry Pipeline Rupture	Tailings slurry pipeline ruptured due to high pressure buildup in a frozen line. The slurry released eroded a "V" cut in the dam face, which led to the escape of approximately 50,000 tons of solids and slimes and somewhere between 2 million and 8 million gal of liquid. All material released was confined to company property.
4/77	Western Nuclear, Inc. Jeffrey City, WY	Failure of Tailing Pond Embankment	Tailings slurry overtopped the embankment due to insufficient freeboard space; considerably less slope than the requisite 3 horizontal to 1 vertical; and a loss in structural integrity occasioned by the melting of snow that was interspersed with fill used to construct the embankment. Approximately 2 million gal of liquid tailings (55 yd^3 of solids) were released. The grind mill and mill yard were completely covered, but no material was released to unrestricted areas.
9/26/77 9/27/77	United Nuclear Church Rock, NM	Release from Tailings Slurry Line	In the process of flushing tailings lines, it was discovered that a 2-inch water line had insufficient pressure to flush out plug. The line was uncoupled and roughly 1/4 ton of tails ran out of the line. With the line still uncoupled, flushing was inadvertently initiated again, resulting in the release of 4,000 gal of flush water and an additional ton of tailings. Approximately 1 ton of solids and slurries and 900 gal of liquid entered the watercourse. The liquid flowing to the watercourse was almost entirely mine water, a portion of which had not been treated (i.e., high in uranium and radium values).