DEVELOPMENT OF HRA-INFORMED PRODUCTS FOR OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS: BYPRODUCT MATERIALS

Briefing to

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Briefing Topics

- Background on development of HRA-informed products for NMSS
- Overview of efforts to develop HRA-informed training & job aids
- Current status & near-term plans
- Long-term view of development plans
- Example from HRA-informed training
- Questions and/or discussion

Background on Development of HRA-Informed Products for NMSS

- User Need (2003-003) from NMSS:
  - Phase 1 feasibility studies to identify NMSS needs were completed by 2005
    1. BNL performed study for byproduct materials (both medical & industrial uses)
    2. Study for high-level waste, fuel cycle, SFPO, & decommissioning was performed in-house
- Based on staff input (HQ & Regions), BNL is now focusing on development of HRA-informed products for medical applications (**gamma-knife based**) :
  - HRA-informed job aid (principally, for license reviewers)
  - HRA-informed training (both general & associated with HRA-informed job aid)
- NRC staff see this project as addressing Commission concerns about human errors in medical applications of byproduct materials, e.g.,
  - SRM issued April 30, 2007 (ML071200265)
  - Presentation & comments from Commission in May 2006

Overview of efforts to develop HRA-informed training & job aids

- Efforts are based on results of Phase 1 feasibility study & additional interactions with staff
- While a variety of different HRA-informed products were identified, development of job aids & training were agreed upon
- Medical applications also was agreed upon as an initial focus
- Staff interactions also helped to identify a list of human performance topics to focus on & gamma knife as "test bed"
- HRA-informed training & job aid are inter-related (so development has been iterative)
- Proto-types of both HRA-informed training & job aid (**gamma-knife based**) have been developed & presented to staff
  - HRA-informed job aid is aimed at supporting license reviewers, but is expected to be more generally applicable
  - HRA-informed training has two parts:
    1. General topics on human error & performance
    2. Specific to job aid & its use

Current Status & Near-Term Plans

- With current resources for FY 2007, expect to:
  1. Present update to staff on general training
  2. Identify new requirements, specifications & recommended developments for HRA-informed job aid
- In the near term, there are additional development efforts that are needed:
  - Based on staff feedback, revision & refinement of HRA-informed training on general topics related to human error
  - New “coding” of job aid (based on identified requirements & specifications)
  - Revisions & refinements of job aid (based on staff feedback)
  - Revision & refinement of associated job-aid-associated training

Also, new User Need is under discussion.

Long-Term View of Development Plans

- Pilot of HRA-informed job aid & training at Region I
- Expansion of HRA-informed job aid:
  - To address other “jobs” (e.g., inspection)
  - To address other modalities (beyond gamma knife)
- Expansion of training
  - Ditto
- Agency-wide roll-out for medical application
- Expansion to address industrial applications

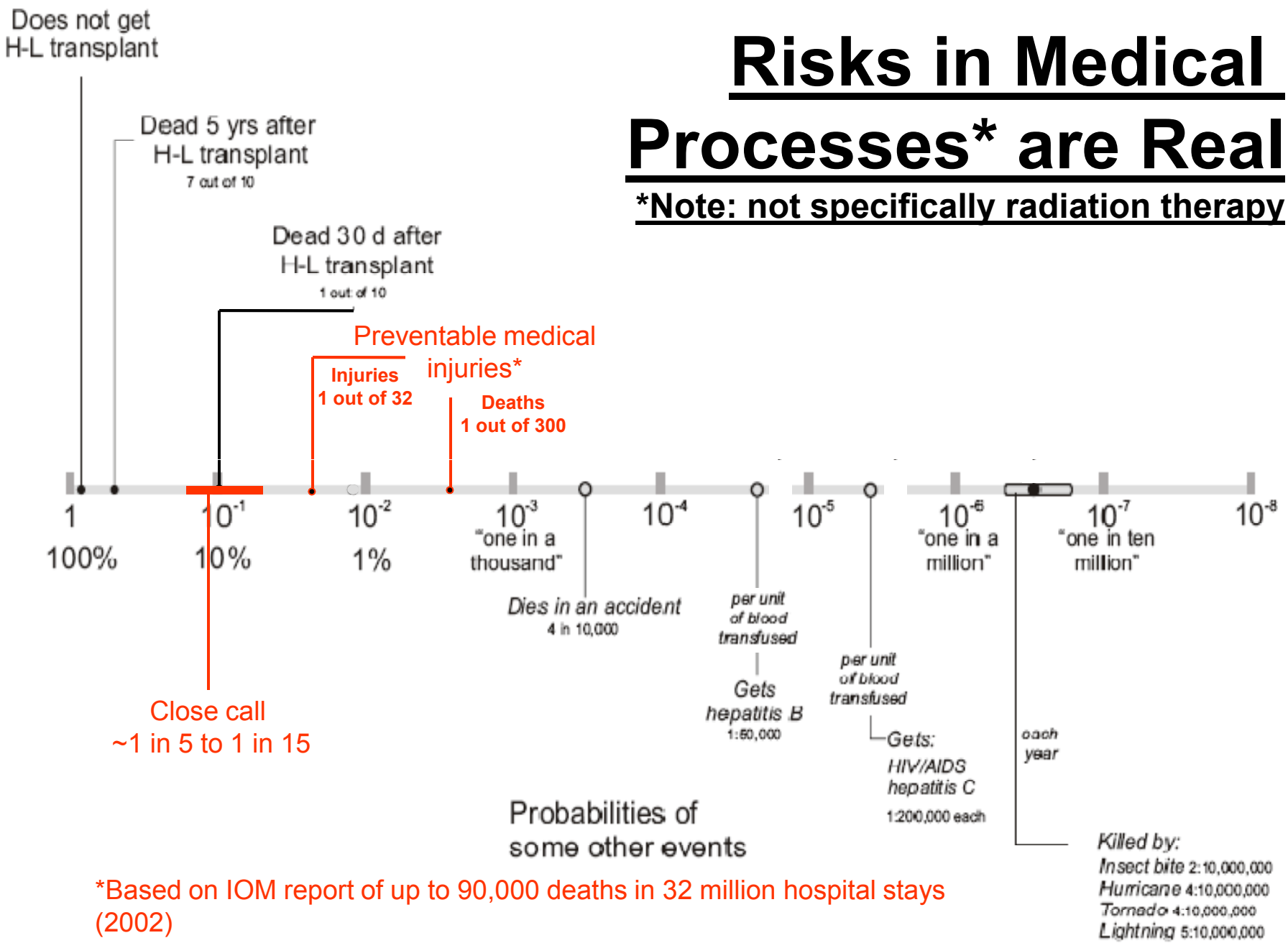
Excerpts from HRA-Informed Training (general topics)

Overview

- Human Error in Medical Applications
- What is Human Error
- Error Mechanisms/Contexts
- Current Thinking on Human Error
- Event Analysis/Corrective Actions

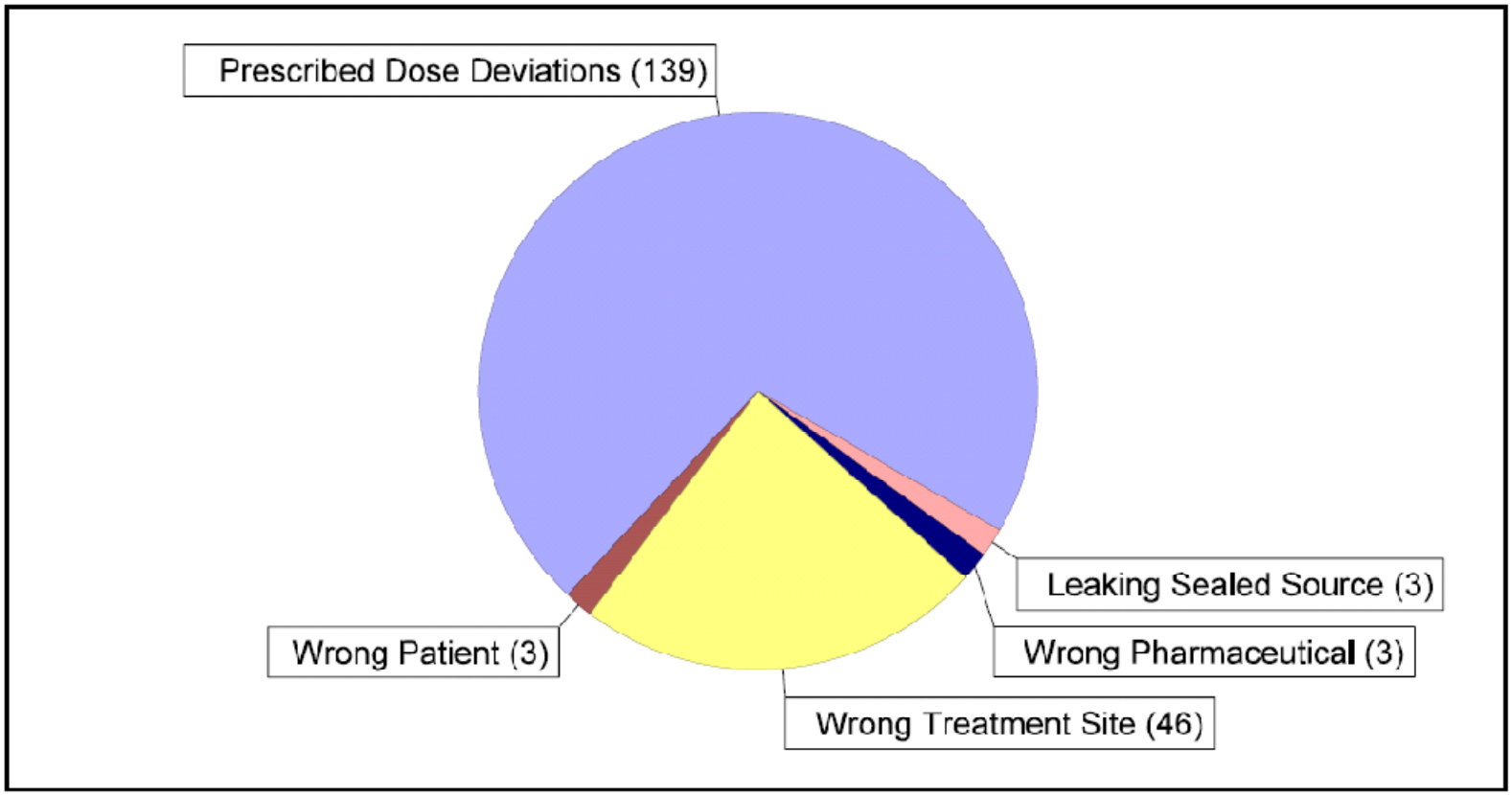
Risks in Medical Processes* are Real

***Note: not specifically radiation therapy**



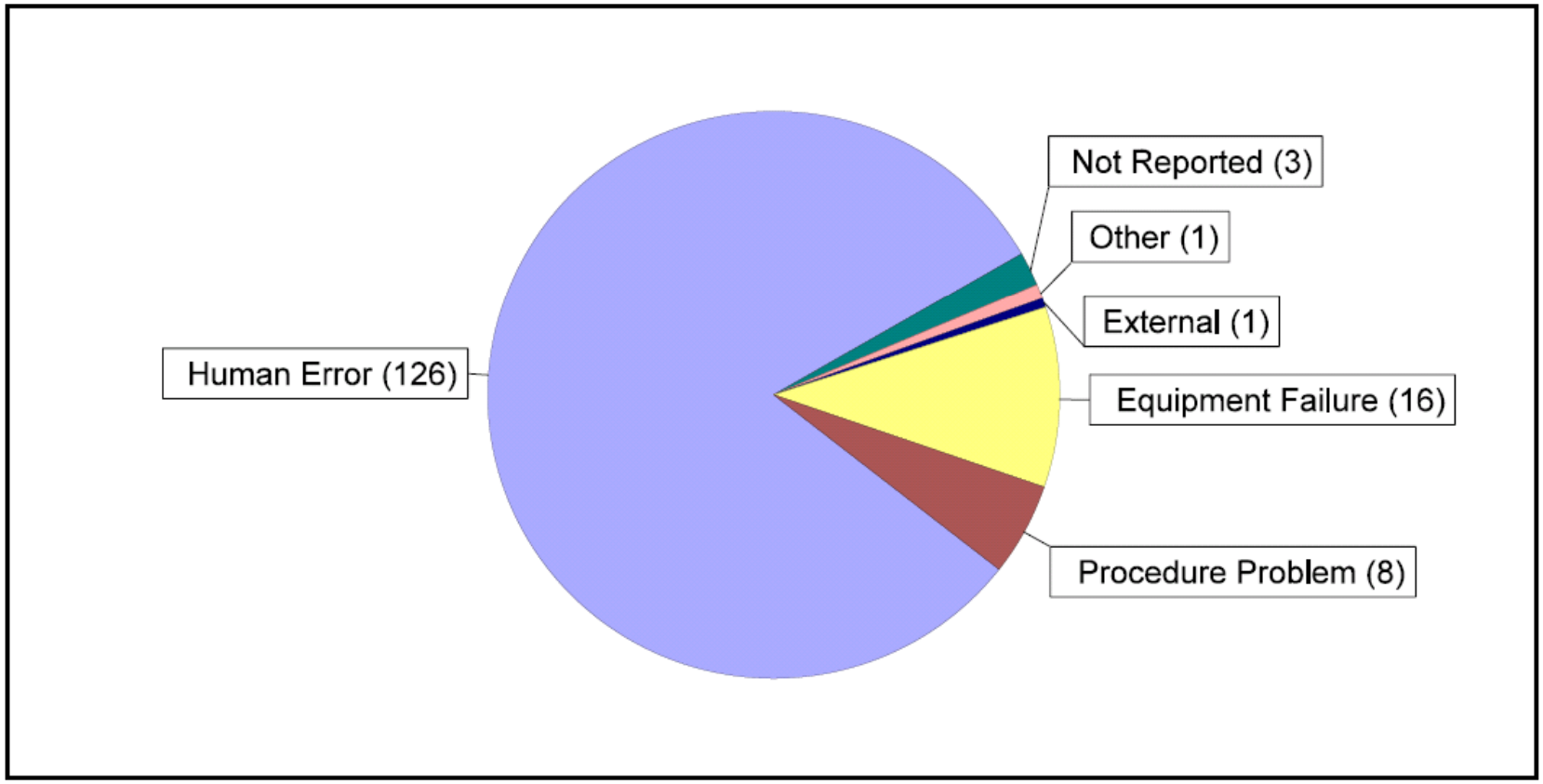
*Based on IOM report of up to 90,000 deaths in 32 million hospital stays (2002)

Types of Medical Events



Source: NMED 2nd Quarter Report FY2007 (last 16 quarters)

NMED Medical Event Causes



Source: NMED 2nd Quarter Report FY2007 (last 16 quarters)

The Search for Root Causes

- The purpose of the root cause evaluation is to ensure fixes are put in place to eliminate or reduce the risks of repeat events
  - "What you look for is what you find" - WYLFIWYF
  - "What you find is what you fix" - WYFIWYF
    - Anticipating problems in license reviews & modifications
    - Reviewing corrective actions
    - Changes in regulations
- Most commonly cited causes in NMED:
  - Inattention to detail (~48%)
  - Failure to follow procedures (~26%)
- There are reasons for this
  - The nature of tasks
  - The nature of human behavior
- But these *do not fully explain* the events
  - The analysis is superficial
  - Corrective actions may be ineffective

Example: Beatson Oncology Centre, 2006

- Beatson Oncology Centre (BOC) major oncology treatment centre in Scotland
- Teletherapy event, but could happen with any modality controlled by computer
  - Varian Varis software (commonly used in rad therapy)
- 15 year old patient dosed in 19 fractions (20 prescribed) each with 58% overdose in January 2006
  - Died October 2006
- Step omitted from planning calculational process
  - Normalization step missed
    - Inattention to detail?
  - Step omitted from procedure
    - Inadequate procedure?
  - Not detected by checker
    - Inattention to detail?
  - Planner not qualified to perform this planning process
    - Violation of rules?

However…

- Software newly upgraded for planning and treatment tools, to allow automatic transfer of data from planning to treatment program
  - Reduction in human errors expected because potential failure mode eliminated
    - Removed manual transcription of data from planning form to treatment software
    - Also expected to reduce costs by eliminating manual actions
      - Reduced treatment prep time estimated to save $35k for avg facility
    - No safety review of impact of changes
  - However because of complexity with this type of tumor, manual calculation of plan was required
    - Only ~6 out of ~5,000 new plans per year
  - Treatment planner omitted <u>new</u> unit conversion step
    - Not identified in procedures
      - Procedure not updated in many years
    - Not detected in reviews by senior planners
      - Planner was more familiar with overall plans like this

And more…

- Beatson had ~40% shortage in treatment planning positions
  - Chronic shortage over many years
  - Not just funds
    - Few Med School graduates want to enter field
  - (US average estimated to be 18.9% shortage for typical Rad Onc Dept)
- Pressure from public for reducing waiting times for treatment
  - Oncology services being consolidated at BOC
  - Reported delays of up to13 weeks for lung cancer treatment
    - 20% avoidable death rate due to delay alleged
- No staff available to maintain infrastructure
  - Procedures
  - Training
  - Reviews of new software
  - Etc.
- So “human error” causes (bad procedures, inattention, etc.) were symptoms of a bigger problem
  - “Fixing” them (e.g., discipline) would not improve things in reality
    - WYLFIWYF
    - WYFIWYF

How to Solve Need

- Our work is to help improve search for the bigger causes of events:
- We are providing:
  - Training
    - Human error in medical applications
    - What is human error?
    - Error mechanisms & contexts
    - Current thinking on human performance in “new technologies”
    - Event analysis & corrective action evaluations
      - Classroom, movies & exercises
  - Knowledge aid software tool
    - Provide & reinforce technical knowledge beyond coverage in training
  - Software aid to support event analysis?

Example ‘Real World’ Analysis

ER, Season 3, Episode 12: *Post Mortem*

Approaching an Event Differently

- Licensee RCAs should show & NRC inspectors should consider:
  - Why did behaviors that are usually effective lead to an event in this instance?
    - *Efficiency & urgency*
    - *Flexibility*
  - Why did barriers that usually prevent events not do so in this instance?
    - *Non-normal staffing & experience*
    - *Workload*
    - *Unusual contexts*
  - Why did the action taken make sense at the time?
    - *Normal routine to rely on "SOP"*
- How do licensee's corrective actions resolve these?
  - Simply telling staff to pay better attention does not fix this event

Questions and/or discussion?