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Attachment 1 – Severity Level Classification Tool Example

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To ensure consistent and reproducible classification of severity levels an evaluation tool that analyzes the cause and effect of a violation in a very consistent and reproducible manner has been developed. Once the bounds of severity of the cause and effect are identified then the tool can be used to determine the severity level of any violation and therefore the level of enforcement action to be taken.

The tool itself consists of the following tables. The first two provide examples of causes of violations and the effect of the violation respectively

Table 1: Cause Severity Level Examples				
	SL-1	SL-2	SL-3	SL-4
General	Failure of Engineering or Process Control	Management failure causing the violation	Worker directly causing the violation	Approved procedure or equipment failure cause violation
Medical	Failure of treatment planning system, interlocks etc.	Quality Management Program failure	AU or staff causing the violation	Approved procedure failure cause violation

Table 2: Effect Severity Level Examples				
	SL-1	SL-2	SL-3	SL-4
Extremity, SDE rem	>150	>100	>50	>25
Lens of eye, LDE rem	>75	>30	>15	>5
100 mrem/y Public TEDE rem	>2.5	>1.0	>0.75	>0.5
500 mrem/y Public TEDE rem	>2.5	>1.0	>0.5	>0.1
Rad worker TEDE rem	>25	>10	>5	>0.1
Medical Event	ME with severe clinical effect or death	ME with permanent clinical effect	ME with non permanent clinical effect	ME with no clinical effect
Release of RAM to unrestricted area	>10 times any limit	>5 times any limit	>1 times any limit with potential for public exposure	>1 times any limit no potential for public exposure
Disposal of RAM	>10 times any limit	>5 times any limit	>1 times any limit with potential for public exposure	>1 times any limit no potential for public exposure
Notifications	N/A	Fail to make immediate notification	Fail to make 24 hr notification	Fail to make 30 day notification

Table 3: Cause or Effect Severity Level Matrix				
	SL-1	SL-2	SL-3	SL-4
Yes	F	D	C	B
No	D	C	B	A

Table 4: Severity Level						
Cause ↓	F	I	I	I	I	I
	D	II	II	II	II	I
	C	III	III	III	II	II
	B	IV	IV	III	III	III
	A	V	IV	IV	IV	IV
Effect →		A	B	C	D	F

Table 5: Enforcement Action		
Severity	Result	% of Base Fine
I	CP	100
II	CP	80
III	Possible CP	50
IV	NOV	15
V	NOV or NCV	5
CP = Civil penalty NOV = Notice of violation NCV = Non-cited violation		

Example:

The following example came from an actual NRC enforcement action in which NRC identified a Severity Level 3 violation but chose to use enforcement discretion and not issue a civil penalty:

At licensee XYZ a violation involved the failure to follow the requirement of their written Quality Management Plan (QMP) to develop a second radiation dosimetry plan based on actual distribution of prostate implant sources relative to the prostate gland as seen by localization radiographs. Specifically, a second radiation plan was not developed after implantation of iodine-125 seeds to assess the actual dose to the patients' prostates (as shown by localization films) for 26 out of 30 patients treated with prostate implants. This failure to follow the QMP did not directly result in any medical events with clinical significance.

Using the examples from the medical row of Table 1, determine from Table 3 which letter score corresponds to the first yes when proceeding from left to right. For example, first ask if this violation was the result of a treatment planning system or interlock failure (from column SL-1 of Table 1). The answer is no therefore go to column SL-2 of Table 1 and ask if the violation was caused by a failure of the QMP. The QMP itself did not fail but since the QMP was not followed then the answer to column 3 of Table 1 is yes, therefore the cause letter score is "C".

Next, repeat the above process using the examples from the medical event row of Table 2. Since this violation did not result in any medical event, the answers to all questions from Table 3 are no and therefore the letter score is "A".

The overall Severity Level is determined from Table 4 by finding the intersection of the Cause and Effect letter scores. In this example, the intersection is at Cause "C" and Effect "A" which yields a Severity Level of III.

From Table 5, it can be seen that this severity level results in a possible civil penalty which is consistent with the action taken by NRC.