Comparison of Clinical Trial and Non-Trial Pass Rates for IROC Houston's HN and Lung Phantoms

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Purpose:

To evaluate and compare passing rates for IROC Houston's HN and lung phantoms irradiated for NCI clinical trials, non-NCI clinical trials and non-trial purposes during the past 5 years.

Methods:

The HN phantom contains a primary and secondary PTV and the lung phantom contains a pill-shaped PTV embedded in lung equivalent material. Both phantoms hold TLD and radiochromic film and are mailed to institutions for NCI trial credentialing, non-NCI trial credentialing and non-trial end-to-end QA purposes. Passing criteria for the HN phantom is: TLD/TPS ±7% and ≥ 85% of pixels passing 7%/4mm gamma analysis and the lung phantom is TLD/TPS within 0.92 – 1.05 and ≥ 80% of pixels passing a 7%/5mm gamma analysis with the average over three planes ≥ 85% of pixels passing, respectively. Pass rates of phantoms irradiated from 2015 to present were calculated and compared using the Pearson chi-squared test.

Figure 1: Image of IROC Houston's solid Head and Neck Phantom.

Results:

The average HN phantom pass rate was 94% with: 94% for NCI clinical trials (N = 412), 95% for non-NCI clinical trials (N = 131) and 93% for non-trial (N = 402) irradiations. They were not statistically significantly different. The average lung phantom pass rate was 86% with: 84% for NCI clinical trials (N = 450), 83% for non-NCI clinical trials (N = 142) and 89% for non-trial (N =513) irradiations. When comparing the lung phantom pass rates given the purpose of the irradiation (NCI, Non-NCI Clinical and Non-Trial), we found that the pass rates were statistically significant (p = 0.016) based on that purpose. In this Pearson chi-squared test, we compared all three purposes of irradiation to show that there is some association with pass rates. This differs from the HN phantom where no association to pass rates was found.

In directly comparing the pass rates between the HN and lung phantom in Table 1 and Table 2, we can observe that the Non-Trial pass rates for lung phantom varies the greatest from the other purposes.

	Pass	Pass (%)	Fail	Fail (%)	Total:
NCI	389	94%	23	6%	412
Non-NCI Clinical	125	95%	6	5%	131
Non-trial	373	93%	29	7%	402
Total:	887	94%	58	6%	945

Table 1: Overall and Breakdown of pass rates for the head and neck phantom from 2015 – current. Pass and fail percentage rates were calculated using the total from each individual section. NCI consisted of all HN phantoms irradiated for the purpose of NCI-sponsored trials. Non-NCI clinical trials consisted of all HN phantoms irradiated for the purpose of trials that are not NCI-sponsored, for example, pharma-sponsored trials and international groups, such as, EORTC. Non-trial consisted of all HN phantoms irradiated for the purpose of personalized QA with no attachment to a clinical trial. This includes IROC Houston's fee service and company/hospital contracts for monitoring.

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Results (cont.):

This suggests that the Non-trial pass rate is the culprit for the association found in the Pearson chi-squared test for the lung phantom, though our test does not exclusively show this conclusion. We do not, however, observe this is the HN phantom which shows almost identical pass rates among all three purposes. The increase complexity of the lung phantom, as compared to the HN, and in combination of their given approach based on their purpose, could explain this discrepancy.

	Pass	Pass (%)	Fail	Fail (%)	Total:
NCI	376	84%	74	16%	450
Non-NCI Clinical	118	83%	24	17%	142
Non-trial	459	89%	54	11%	513
Total:	953	86%	152	14%	1105

Table 2: Overall and Breakdown of pass rates for the lung phantom from 2015 – current. Pass and fail percentage rates were calculated using the total from each individual section. NCI consisted of all lung phantoms irradiated for the purpose of NCI-sponsored trials. Non-NCI clinical trials consisted of all lung phantoms irradiated for the purpose of trials that are not NCI-sponsored, for example, pharma-sponsored trials and non-NCTN groups, such as, CPRIT. Non-trial consisted of all HN phantoms irradiated for the purpose of personalized QA with no attachment to a clinical trial. This includes IROC Houston's fee service and company/hospital contracts for monitoring.

Conclusion:

The differences in the lung phantom pass rates may be due to increased difficulty of the lung phantom. Perhaps the non-trial sites irradiated the phantom at the time of system commissioning and were paying closer attention to detail during irradiation than the other irradiations.