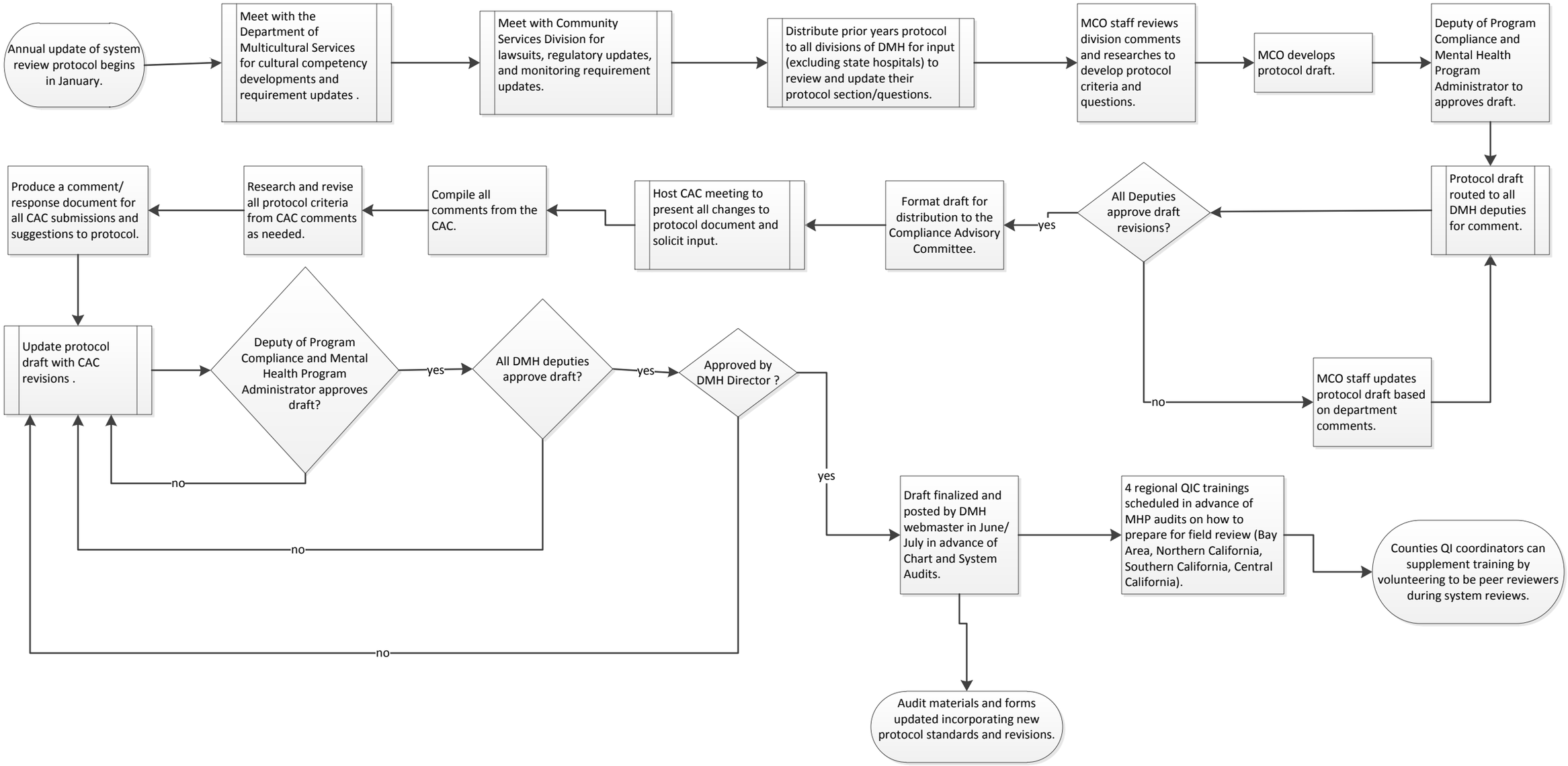Exhibit I - Protocol Development